

India's Forward Momentum in Pharmaceuticals

Elizabeth Nesbitt, Office of Industries
(Elizabeth.Nesbitt@usitc.gov, 202-205-3355)

A major producer and exporter of formulated, low-cost generic pharmaceuticals, India increased its exports to major markets during 2011–17, including sub-Saharan Africa (SSA) and the United States. India is also taking steps to produce more innovative pharmaceuticals through such measures as accessing U.S. technology through mergers, acquisitions, and licensing, and by also adding and expanding production and other facilities in the United States.

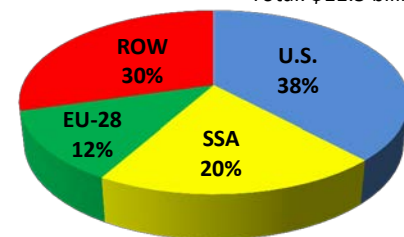
India's Trade Flows and Major Export Market Characteristics

India imports substantial volumes of bulk active pharmaceutical ingredients, largely from China, and formulates them into consumer dosage-form products.¹ India's global exports of **formulated products (Harmonized System 3004)** in 2017 totaled \$11.5 billion, and were shipped mainly to the United States, sub-Saharan Africa (SSA), and the European Union (EU-28) (figures 1 and 2).

The U.S. pharmaceutical market is a major destination because of its large size (about \$450 billion in 2017), strong consumer demand, and the importance of the generic product segment (over 20%).² During 2011–17, U.S. imports of formulated products from India almost doubled to \$6.0 billion, accounting for 85-90% annually of total U.S. pharma imports from India.³ India's exports of formulated products to SSA also increased substantially over the period (by 64%), reflecting the region's growing national healthcare expenditures, expanded rural access to pharmaceuticals, and more instances of non-communicable diseases such as cancer, all of which portends its market growth potential.⁴ India's exports of such products to the EU-28, however, only increased slightly during 2011–17, from \$1 billion to \$1.4 billion.⁵

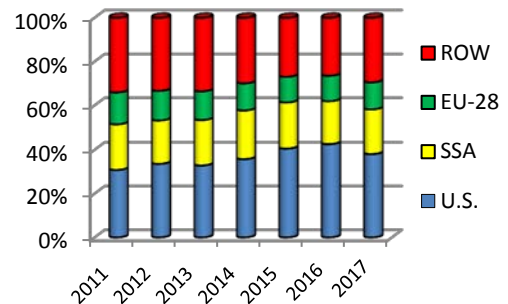
Despite export growth, quality/safety concerns likely tempered India's exports to these markets. For example, Indian firms received about 46 warning letters related to good manufacturing practices from the U.S. Food and Drug Administration (FDA) during 2013–17;⁶ warning letters are issued for "violations of regulatory significance."⁷ In SSA, concerns have been raised that India sends lower quality products to Africa, as well as counterfeit products.⁸ Further, the EU banned 700 generic products from India in 2015; French and German regulatory agencies addressed the manufacturing practices of two Indian companies in 2016.⁹

Figure 1. India's export markets for formulated products, 2017
Total: \$11.5 billion



Source: Global Trade Atlas (accessed March 27, 2018).

Figure 2. India's world pharmaceutical exports, 2011–17



Source: Global Trade Atlas (accessed March 27, 2018).

¹ Singh, "[India's Pharmaceutical Prescription is Unhealthy](#)," *Nikkei Asian Review*, November 12, 2017.

² IQVIA Institute for Human Data Science, "[Medicine Use and Spending in the U.S.](#)," April 2018, 3. Spending is on an invoice basis.

³ DataWeb (for HS heading 3004; accessed March 27, 2018).

⁴ IHS Markit, Global Trade Atlas (for HS heading 3004; accessed March 27, 2018).

⁵ Ibid. The United States and Switzerland supplied over 80% of the EU-28's \$38 billion in imports of formulated products in 2016.

⁶ Unger, "[An Analysis of FDA FY2017 Drug GMP Warning Letters](#)," January 10, 2018. Also, Singh, November 12, 2017.

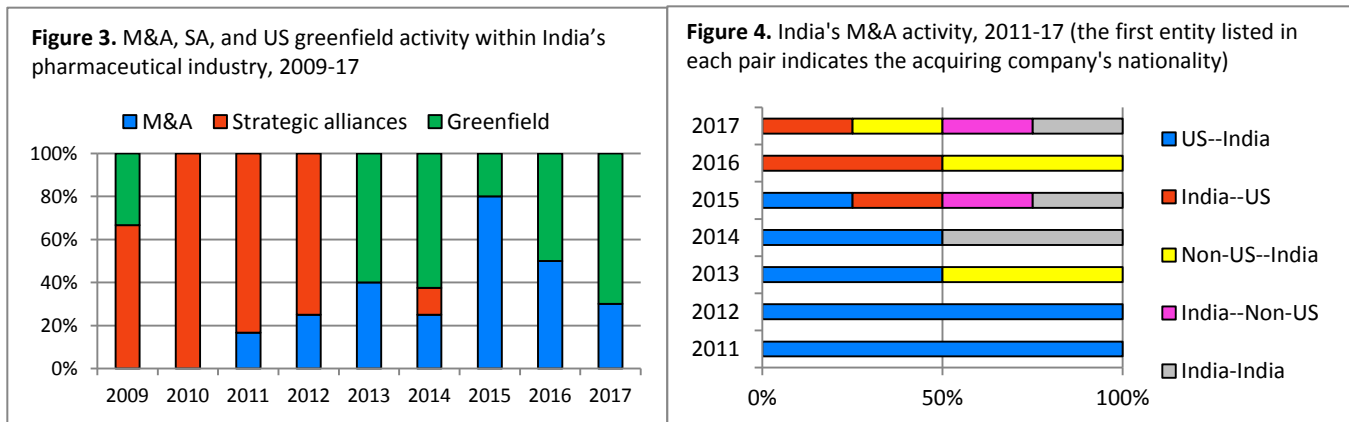
⁷ FDA, "[Regulatory Procedures Manual: 4-1 – Warning Letters](#)," May 2, 2016. The FDA says in the manual that the letters allow companies "an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action."

⁸ Lo, "[Nurturing an African Pharma Boom](#)," *Pharmaceutical Technology*, July 25, 2016; Horner, "[India's Pharmaceuticals, Local Production and Public Health Security in sub-Saharan Africa: A Comparative Study](#)," n.d.; Webb, "[A Bitter Pill to Swallow: The Problem of, and Solutions to, Sub-Saharan Africa's Counterfeit Pharmaceutical Trade](#)," *Journal of Global Health*, November 1, 2014.

⁹ Singh; also Kazmin and Ward, "[Generic Drugs Ban Prompts India to Freeze EU Trade Talks](#)," *Financial Times*, August 5, 2015.

Investment flows

A review of 55 projects involving Indian companies during 2009–17 reveals that Indian outbound pharma investment flows to their main markets (the United States, SSA, and the EU-28) have been shifting from strategic alliances (SA) towards mergers and acquisitions (M&A) and the development of new/expanded Indian greenfield facilities in the United States (figure 3).¹⁰ Looking at just M&A activity, the review also shows that Indian companies accounted for a large share of acquisitions in recent years (figure 4).¹¹ Sources attribute the increased Indian M&A and greenfield activity, in part, to long-term strategic positioning and Indian companies' "strong cash flows, low leverage, and high debt capacity."¹²



Source: Both compiled from IBEF, "Pharmaceuticals," January 2018; fDi Intelligence, from the *Financial Times* Ltd., 2018; and other sources.

Factors spurring Indian investment in the United States include: (1) the large U.S. generics market and its potential for expansion given the expiration of U.S. patents on about \$55 billion of products during 2017–20; (2) access to U.S. firms' best practices in complying with FDA requirements; (3) entry into market segments requiring U.S. production (e.g., controlled pharmaceuticals); and (4) expanded access to innovative pharmaceutical products developed and manufactured by the U.S. industry. Although quality problems are still reported,¹³ new products are emerging from Indian-U.S. collaborations. For example, Mylan announced in December 2017 that the FDA had just approved a new pharmaceutical—a biosimilar to treat certain cancers—developed during its 8-year collaboration with Biocon.¹⁴

Sources: References in footnotes, as well as *The Dollar Business*, "Indian Pharma exports to US may increase in 2018, *Care Ratings*," August 30, 2017; India Brand Equity Foundation (IBEF), "Pharmaceuticals," January 2018; Pant, "Indian Pharmaceutical Exports: The Growth Story," January 6, 2016; Raghavan, "India Maintains Lead over China in Pharma Exports in 2015," *The Economic Times*, July 5, 2016; Seth, "United States Imports Only 25% of Its Drugs," Investopedia, January 20, 2017; Abdallah, "Why Big Drug Firms are Seeking New Markets in Africa," *The East African*, July 30, 2016; EMIS, "Sub-Saharan Africa: In Sickness and In Health," n.d.; Ashley, "Center for Drug Evaluation and Research—Compliance Central with FDA Center Compliance Directors: Part 1," FDA, Presentation at 2017 FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries, December 6, 2017.

¹⁰ In addition to the United States, outbound Indian M&A activity and greenfield investment also involved partners in Asia, Canada, Europe, Mexico, the Middle East, Russia, South America, and SSA, among others.

¹¹ The M&A activity shown includes units/brands and whole companies. IBEF and other sources. One example of Indian greenfield activity in the United States is Glenmark's 2017 expansion of two U.S. facilities it started up during 2014–16. Calio, "Glenmark Pharma to Expand Paramus Facility," *NJBix*, October 2017.

¹² Das and Phadnis, "Japanese Lender Key Financier of Pharma M&As"; also, *Business Standard*, January 26, 2017; NASDAQ, "India's Generic Drug Manufacturers: Poised for Continued Growth," February 29, 2016; Summerfield, "M&A in the Pharmaceutical Sector," *Financier Worldwide Magazine*, December 2014.

¹³ Generics & Biosimilars Initiative, "Setback in Biocon/Mylan's Biosimilar Programme after GMP Inspection," November 8, 2017.

¹⁴ Mylan, "U.S. FDA Approves Mylan and Biocon's Ogivri™, the First Biosimilar for Trastuzumab, for the Treatment of HER2-Positive Breast and Gastric Cancers," press release, December 1, 2017.