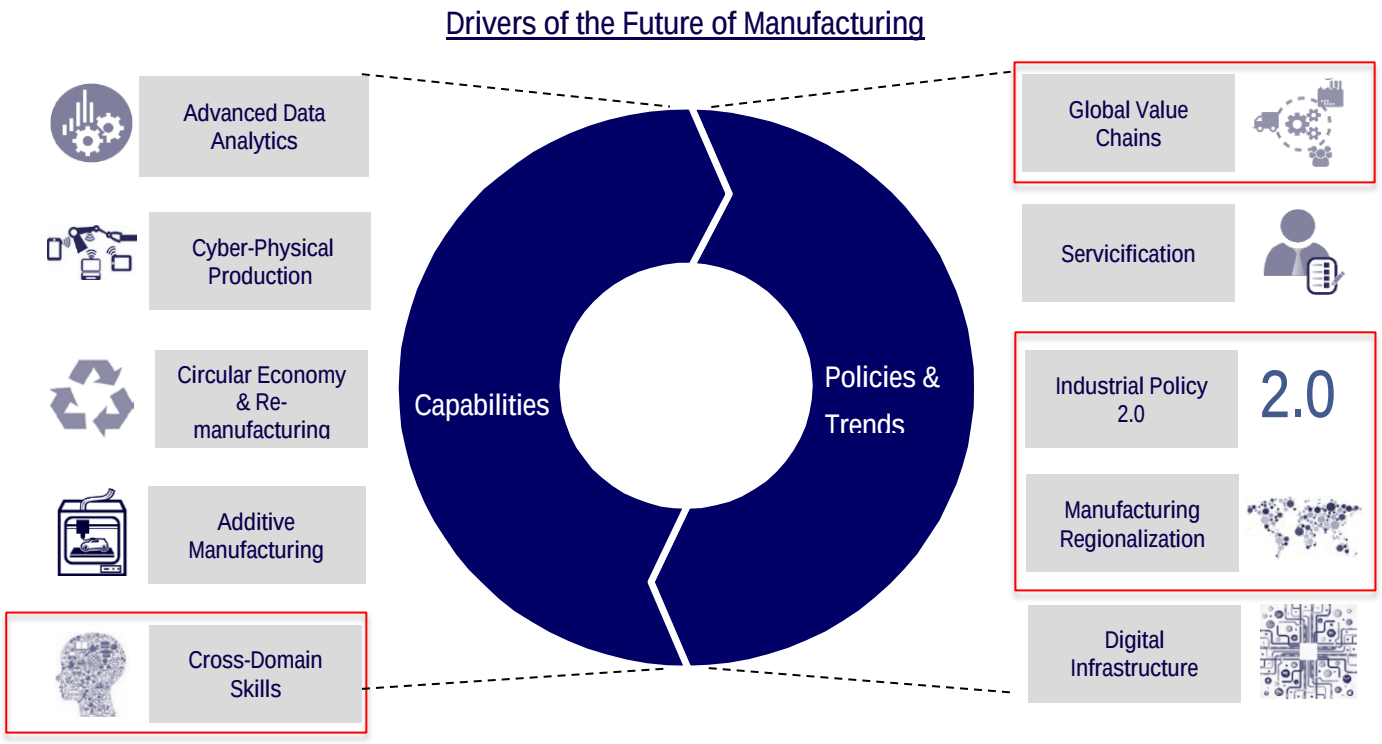
Case 3

Brazilian Technological Trajectory in the Pharmaceutical Industry



Source: World Economic Forum Global Agenda Council on the Future of Manufacturing, Whiteshield Partners framing

Executive Summary

1. Challenge Confronted

In the 1990s, the Brazilian **pharmaceutical industry had consolidated** a position based much more **on the marketing activity than on the research and development** (R&D) necessary for innovation. On the one hand, global multinationals dominated the local market, following a restrictive logic on its investments. Their activities within Brazil were somewhat **disconnected from their more innovative global activities**; they focused on manufacturing products with little local aggregate value, or acting as traders. On the other hand, domestic pharmaceutical companies were impressive, using a restricted portfolio of low-cost, "me-too" drugs that did **not encourage greater efforts at innovation**.

2. Solution Used

- In 2003, **industrial policy** came back to the centre of the political agenda and selected **pharma as a key sector**, among a few others. This allowed various government agencies to work together within a shared objective. **The Brazilian Development Bank (BNDES) was chosen to lead the discussion**.
- **The generic drug law of 1999**, tied to a fast-growing middle class, created an unprecedented market opportunity for the growth and technological upgrade of local pharmaceutical companies.
- **The Brazilian National Health Surveillance Agency (ANVISA) – similar to the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) – has policies with high standards** like those of the FDA and EMA: good manufacturing practice (GMP) requirements (2003) and a special biotech pathway (2013).
- **The BNDES Profarma programme (2004-today)** is a long-term debt programme designed to consider the maturity level of Brazilian companies. Profarma had a key role in financing the investments required for implementing the new ANVISA-GMP standards; since the beginning, it has also stated the importance of R&D activities and infrastructure.
- **Partnerships of Productive Development (PDP)** by the Ministry of Health (2008) **define strategic products** for the Brazilian National Health System (SUS), and then induce cooperation between public institutions and private entities for **transferring technology**.

3. Lessons Learned

1. **Defining clear policy objectives** is paramount to ensuring **cooperation** among state institutions and **legitimation** within a democratic country.
2. Capacity is required to **identify international trends, local opportunities and capabilities** to design and implement a **robust** and productive development strategy.
3. A **high-quality mindset** is important for competing with other low-standard export-oriented emerging countries (mainly India and China) in the local market.
4. Finance instruments work better with clear policy objectives (**targeted and mission-oriented finance**) adapted to clients' needs.

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Key facts:

- To build a consensus and a call for action, Brazilian industrial policy deliberately targeted the pharmaceutical industry.
- Industrial development is understood as a dynamic process, requiring different instruments and policies that co-evolve at each stage.
- The strategy involved both incentives (financial support, market opportunities) and requirements (regulation, technology transfer).
- BNDES's actual work went far beyond its mandate as a government finance agency; it identified market and cooperation opportunities, leveraging its investments.
- Other government agencies, such as ANVISA and the Ministry of Health, must be convinced that they do not have neutral roles in economic development.

Description of the Work Performed

In the early 2000s, the discussion about innovation in the Brazilian pharmaceutical industry was in a lock-in situation; to develop just one new drug, it was argued, $1 billion dollars and ten years were required. Both the Brazilian government and small, local private companies could not afford it, given the inherent budget restrictions of a developing country. Meanwhile, local companies were struggling to deal with the new patent law (1996), which hindered the "me-too" strategy and the emerging markets' low-price, export-driven competition. The solution proposed by BNDES to solve this lock-in was to build a roadmap that could lead the country on the technological trajectory to have an industry genuinely based on science and R&D – not as a starting point, but as a final goal.

Since radical innovation in pharma requires large amounts of long-term and patient investment, small companies do not thrive without larger companies serving as partners. Thus, the first step would be to strengthen local companies so that they could stand the financial requirements for new-drug R&D. From the SUS standpoint, the issue of the quality of drugs offered to the Brazilian population was becoming increasingly problematic. In that context, BNDES and ANVISA joined forces: in 2003, ANVISA increased the regulatory requirements for drugs commercialized in Brazil, while in 2004, BNDES offered financing to any company that needed to invest to meet the new GMP requirements. That policy found fertile ground in the emerging middle class's growing local demand for medicines, encouraged by the Brazilian government's antipoverty policies and the Generic Drug Act (1999).

This first approach was very successful in the initial years and, by 2008, was complemented by technology transfer agreements led by the Ministry of Health and known as PDPs (productive development partnerships). After publishing a list of strategic medicines, those partnerships can be settled between stated-owned labs and private companies, encouraging the local production of a few strategic active pharmaceutical ingredients (APIs), such as for HIV drugs.

In the early 2010s, the BNDES team identified another market opportunity for the technological upgrade of local companies – the so-called “patent cliff”, in which many high-valued biotech products reached their patent-protection term. That would allow competition within the biosimilars, with much higher barriers to entry than in the traditional generics market. By 2012, cooperation between the Ministry of Health and BNDES brought biotechnology medicines (mainly monoclonal antibodies) onto the PDP agenda, representing both the industrial challenge of a new technology platform and the health system challenge of incorporating those high-cost products into a limited budget. In this context, ANVISA also played its role, designing specific pathways in 2013 for a biosimilars registry, inspired by the European Medicines Agency.

Now in implementation (2016), Brazil’s biotech strategy uses the PDP model to encourage cooperation between local companies and big foreign pharmaceutical firms. BNDES Profarma Biotechnology, a debt line designed in 2013, finances the required investments by offering special under-inflation interest rates for any company looking to invest in developing and producing biotech products in Brazil.

Nevertheless, the industry's trajectory is not completed. After building capabilities in GMP production, synthetic generics development, incremental innovation, and biotechnology development and production, Brazil’s next challenge is to propose and develop new drugs, joining the global drug innovation agenda. This will probably require other policy instruments, such as promoting venture capital, the start-up environment and the R&D services value chain (mainly clinical trials).

Key Outcomes

- Local companies’ market share grew from 35% in 2003 to 56% in 2015.

- R&D investments grew from 0.6% of revenues in 2003 to 3% of revenues by 2011. If only local companies are considered, R&D efforts are currently over 6% of revenues, which is still far from key global companies but shows consistent improvement.
- Shared objectives were created between different state agencies, and between the state and private companies.

Drivers & Enablers

Policy & partnerships

Capital investment

- Innovation
- Capabilities
- Local production

Barriers

- Inability of small-sized companies to bear the required investments
- Development of R&D service providers' value chain (preclinical and clinical testing, among others)
- Strong competition from emerging countries, especially on producing APIs
- Development of new biological and synthetic drugs