

The Role of the Regulator in Technology Transfer



Theme – Before and Beyond Registration

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OUTLINE



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- **Possible Solutions**
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General Background



INDIA as example

- third largest in terms of volume
- **thirteenth largest in terms of value,**
- 20 % in the volume terms and **1.4 per cent in value**
- largest provider of generic drugs globally
- large pool of scientists and engineers
- 80 % of the antiretroviral supplied by Indian pharmaceutical firms.



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General Background...conti



Some of the relevant government Initiatives

- The pharmaceuticals sector attracted cumulative FDI inflows worth US\$ 15.570 billion between April 2000 and September 2017, according to data released by the Department of Industrial Policy and Promotion (DIPP).
- Private equity and venture capital (PE-VC) investments in the pharmaceutical sector have grown at 38 per cent year-on-year between January-June 2017, due to major deals in this sector.
- 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture.
- Approval time for new facilities has been reduced to boost investments.



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General Background...cont



SADC Pharma Manufacturing Action Plan as part of Regional Strategy

- At least 45% of generic ARVs and 50% of essential medicines are manufactured in SADC as finished dosage forms (by volume)
- harmonize regulatory standards
- 5 Centres of Pharmaceutical and Regulatory Excellence
- Harmonize the standard treatment guidelines for three diseases at regional level
- Facilitate Technology transfer within and towards SADC
- Develop an appropriate mix of industry incentives and instruments
- Create conducive enabling environment



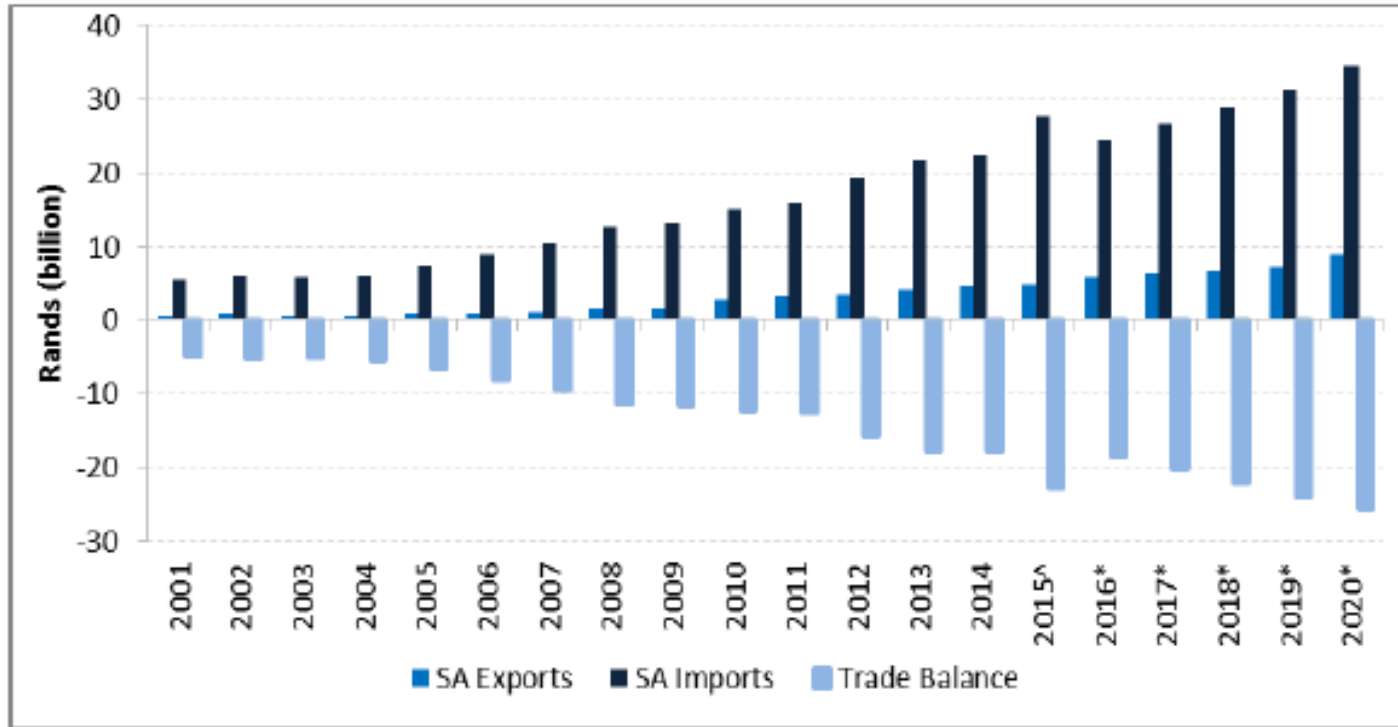
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General Background...cont



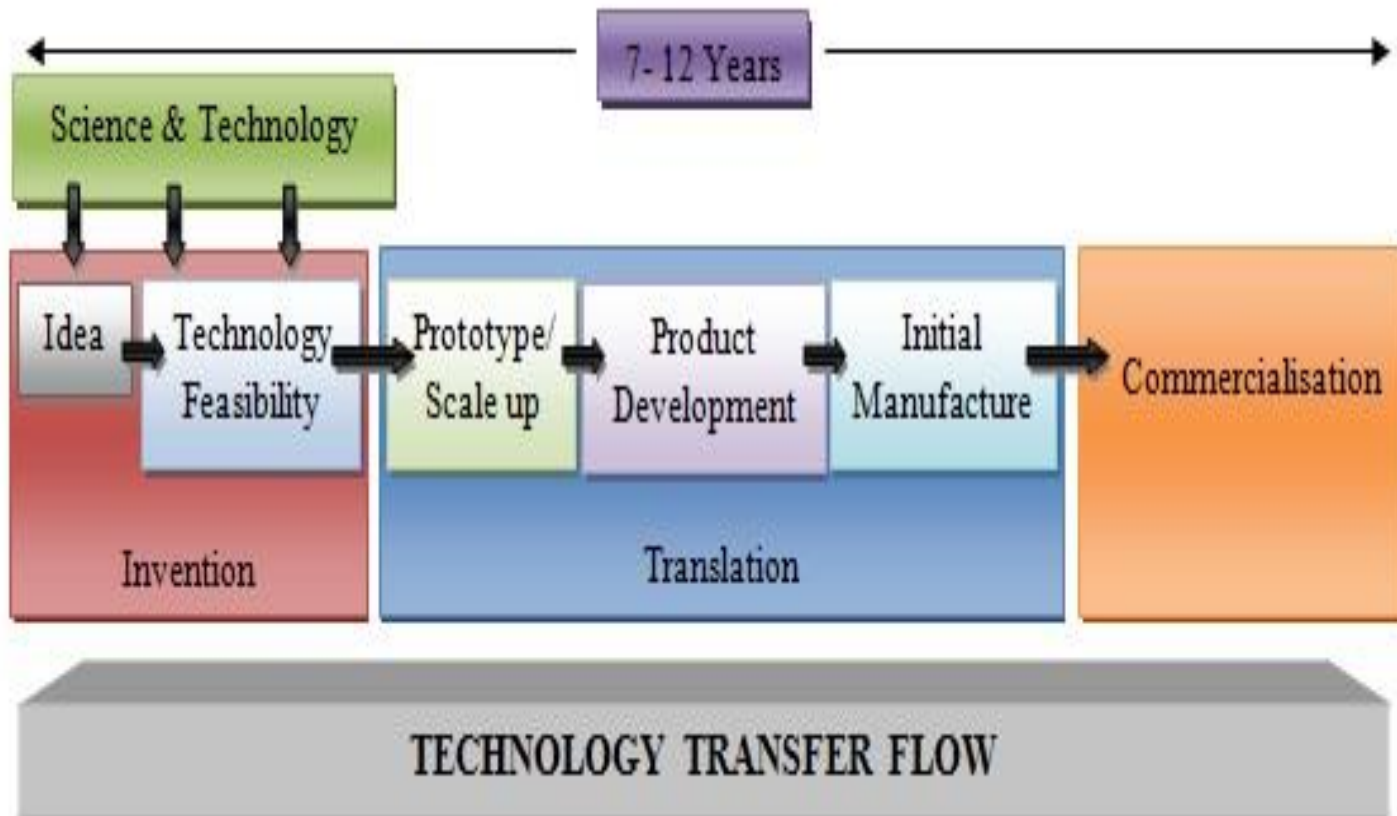
Data Extracted from: Trade Map, 2016; Quantec, 2016; BMI 2016a & BMI 2016b



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What is Technology Transfer



- Rahul Dogra *et al*



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What is Technology Transfer...cont



Technology Transfer

Commercialisation

Transfer manufacturing capacity to a different site

Control Procedures



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What is Technology Transfer...cont



It is the process by which an original owner of technology makes its technology available to others to exploit. Some elements to consider are

- **preparation of technology transfer protocol, report etc**
- **critical process parameters (CPPs),**
- **critical quality attributes (CQAs)**

For details about aspects of Technology transfer refer to *WHO Technical Report Series, No. 961, 2011 other guidance document, e.g. Q8, Q9 and Q10*



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Who should be involved



- Academic institutions
- Manufacturing companies
- Research institutions
- Government
- Regulators
- Labour



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Reasons for Technology Transfer



- **Regulatory** – laws that protect local production in countries (protectionism tendencies), especially in drug manufacturing or perhaps testing, making technology transfer for foreign companies a more attractive option.
- **Competitive Pricing** – local manufacturers in other countries could lead to cheaper production and labour costs, thereby reducing the cost of medicines manufacturing
- **Additional capacity**– Companies' manufacturing capability can potentially increase, eventually transforming into actual savings
- **relocation of operations**- allows corporations to break into untapped markets
- **consolidations and mergers/acquisitions** – taking advantages of economies of scale



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Barriers to Technology Transfer



- **economic**, poor economy and environment, market size and potential
- **lack of skills**, scientific environment in the recipient country
- **IP protections provisions**,
- **high prices**, lack of control of prices
- **high cost**, high manufacturing cost e.g. rental, labour etc.
- **regulatory burden**, **very long approval timelines**



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Possible Solutions to Encourage Tech Transfer



- Foreign Direct Investment (FDI) policy in the pharmaceutical sector
- **prioritise regulatory submission**, supportive regulatory environment, the regulatory function must be efficient and transparent for technology transfer to be economically viable,
- Academic research - efforts on technologies of significant social benefit to the developing nations (R&D, technology transfer institutes etc.), e.g. biologicals, that now account for over a third of all new drugs in clinical trials or awaiting FDA approval (*as per 2016 ITA Pharmaceuticals Top Markets Report*)



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Possible Solutions to Encourage Tech Transfer



- **consider incentives schemes e.g.** through tax breaks and other forms of incentives designed
- **create enabling conditions for innovations , such as access to world-class researchers, political and financial stability, and **regulatory framework****
- **protect and rewards innovation.**



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Possible Solutions



- prioritise regulatory submission, academic focus, (R&D, tech transfer institutes etc.), honest
- communication between sending and receiving units
- innovation cannot happen without a number of enabling conditions, such as access to world-class researchers, political and financial stability, and a regulatory framework that
- protects and rewards innovation. NOTE: All countries have the potential to foster innovation
- and improve the functioning of the innovation process.



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Possible Solutions



- Communicate and collaborate with industry in the preparation of the technology transfer
- Regular quality updates and reporting



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Conclusion



Areas of focus

- create enabling environment for FDI in the pharmaceutical sector
- academic research focus - efforts on technologies of significant social benefit to South Africa
- skills development focus on pharmaceutical manufacturing and
- reduce regulatory burden- collaborative process between the industry and the regulator .e.g. Pre-IND process
- Work to reduce service economy to manufacturing economy
- BBBEE



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Acknowledgement



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THANK YOU



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