International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA

The role of technology transfers in sustainable access to vaccine innovation

Conditions for success

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Summary

- Definition of technology transfer
- Historic landscape
- Lessons learned
- Conclusion

What is a Technology Transfer?

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What	• Transfer of skills, knowledge, technologies, methods of manufacturing, quality management systems, facilities • Activities that involve a capacity-building component at the recipient site intended to enable the recipient to produce quality vaccines • Within or outside an organisation, a geography or an industry/discipline/sector
Why	• To increase access to scientific and technological developments • To allow further development/adaptation and exploitation of the technology into new products, processes, applications, materials or services • To increase innovative products availability • To increase production capacity to meet demand • To meet the mutual business needs of both partners • To promote development of local industry

Which types of technology transfer?

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- A wide range of health-related technologies and processes can be transferred to developing countries:
  - R&D capacity
  - Clinical trials
  - Laboratory testing
  - Quality assessment and system alignment
  - Regulatory capacity
  - Supply chain management and logistical issues
  - Training of personnel / HR management
  - Information technology systems
  - Step-wise local production

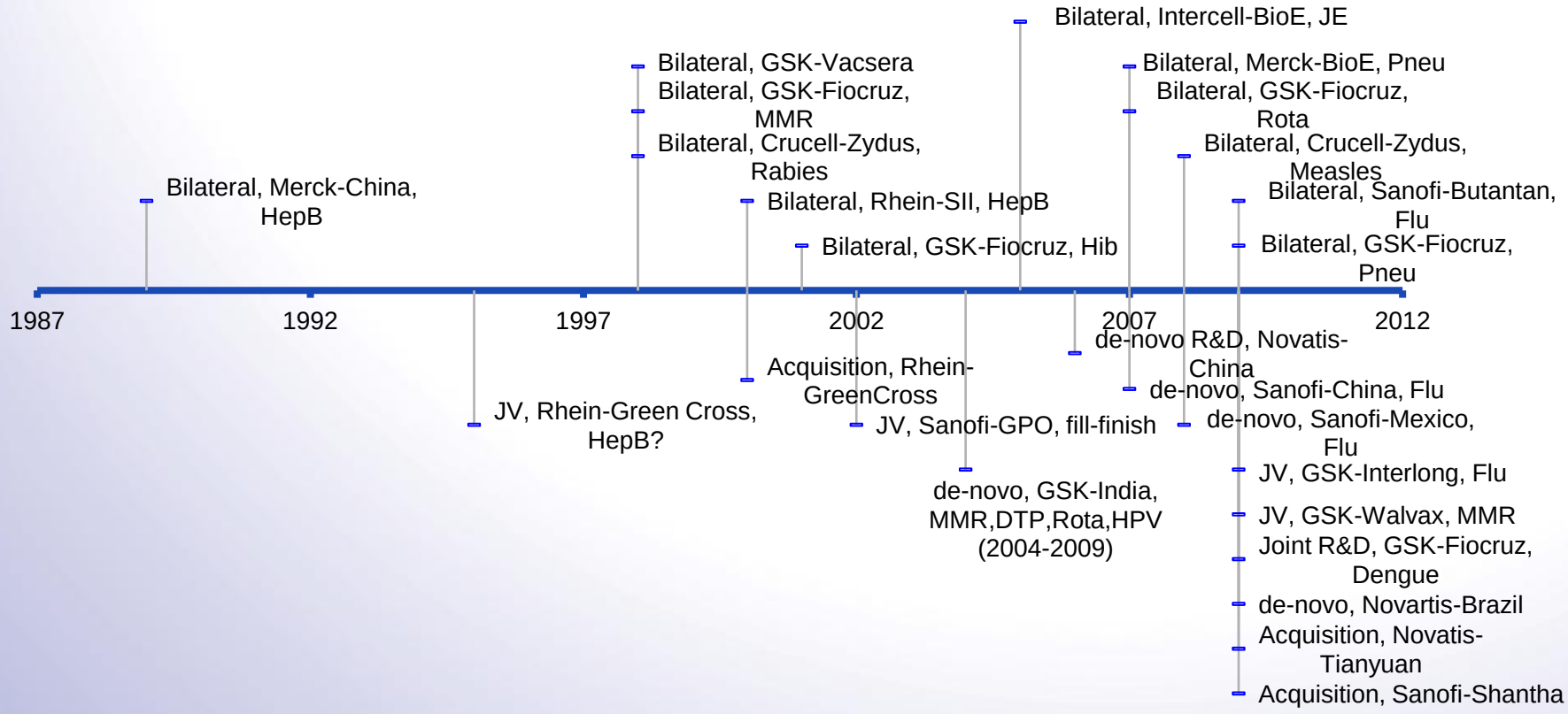
Many of these are not solely in the remit of industry

Unique features of vaccine TT

	Medicines	Vaccines
Tech natures	Various, chemical synthesis may be easy to establish	Complicated
Intellectual property	Product patents are for newer drugs	Product patents less common, but know-how is critical
Market force	Private sector dominated	Highly national policy regulated; global procurement
Market dynamics	Various, good competition for generics	•Limited N of R&D-based manufacturers •>90% vaccines by 15 companies •IFPMA + DCVMN players •fewer TT's
Public Health Impact	Varying impact of drugs on prevention and treatment	Vaccines generally cost-effective and may be cost-saving

History and trends in TT *(Gong, 2010)*

Building capacity: significant **increase** in major Vaccine technology transfers within **private sector** over the last 25 years



History and trends in TT (Hendriks, 2012)

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- 90 confirmed international initiatives for over 14 different vaccines in past 25 years

- 6 different approaches:
  - bilateral know-how transfer (GSK-Fiocruz*: Hib, MMR & MMRV, rota, pneumo, dengue co-development*)
  - joint ventures & acquisition (sanofi-GPO / Merieux)
  - de novo manufacture (GSK Singapore)
  - single recipient joint development with facilitation entity (MVP-SII: *MenA*)
  - shared technology platform (NIH/PATH-Shantha: *rotavirus*)
  - technology transfer hub (various: *flu pandemic*)

- 29 initiatives (1/3) resulted in national license, of which 9 (10%) obtained WHO preQ

High or low success rate?

«Dutch experience» (RIVM)

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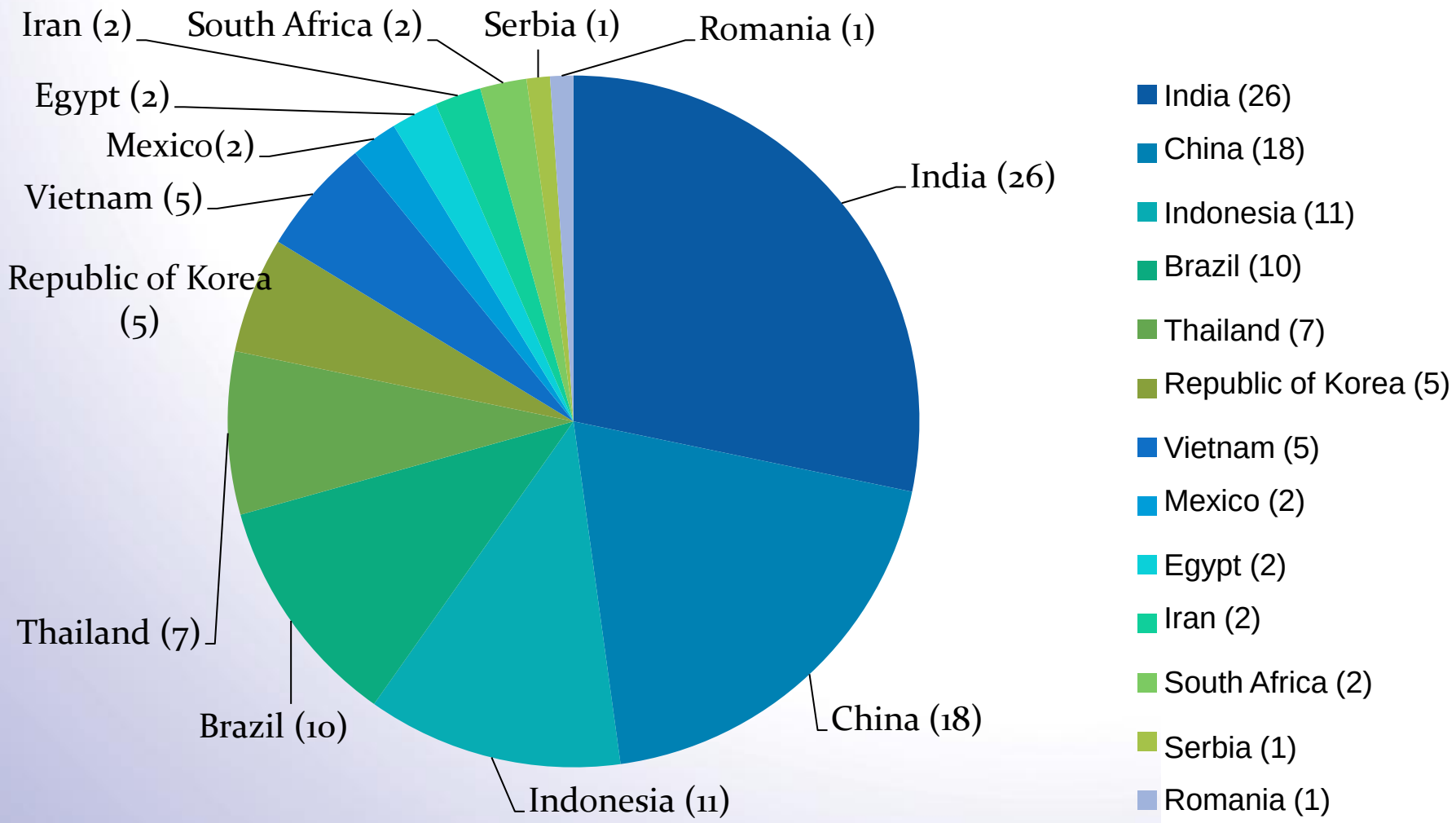
Successes	– DTP, TT – BioFarma, IVAC (Indonesia, Vietnam) – animal-free cultivation for rabies production – IPT (Tunisia) – upgrading combo DTP-HepB – BioFarma – Hib / penta – BioFarma, SII, Biological E, Glovax-SIBP **100% of local needs met !**

Challenges	– DTP, measles, OPV to China state institutes (1990-1997)
	  – funded by World Bank, Rockefeller Foundation and Dutch ODA
	  – 550 person/months training provided to 80 employees (QC/QA)
	– Issues and lessons:
	  – payment disputes, supervision inadequacies, delays
	  – cost of “better quality” vaccine from new facilities too high
	  – complexities exceeded provider capacities & recipient capabilities
	  – perceived “community health project” turned out to be a complex industrial transfer undertaking; **project closed in 1997**
	– positive: human capital development, know-how, GMP & Quality concepts

Recipient countries landscape



Determinants of vaccine innovation for developing countries (Mahoney, 2011)

- appropriate design & execution of research & development programmes from pre-clinical studies to licensure
- marketing & distribution of new technologies in individual developing countries
- procurement & supply of new technologies by global health community
- **planning & implementation of manufacturing capabilities**
- Implementation of a regulatory system to ensure safe and effective products (meeting uniform high quality standards)
- implementation of Intellectual Property (IP)

All determinants must be addressed for success. **TT is only one part** (as is IP).

Attributed values of technology transfer

Technology Transfer is considered by different stakeholders as a way to:

- Increase vaccine access and capacity
- Lower Cost of Goods
- Increase local employment and wealth
- Stimulate local industry and entrepreneurship
- Share Know-How
- Share Intellectual Property

"Give a man a fish, he'll eat for one day; teach a man to fish, he'll eat for lifetime"

Stepwise approach proves to be most successful

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A stepwise approach securing downstream processes prior to developing bulk production capacity

Phase 1

Packaging and distribution of finished product

Implementation of :

- Basic Quality Control
- Labeling
- Cold chain
- Distribution network
- Adverse event reporting
- …

Phase 2

Phase 1 + Filling of bulk

Implementation of :

- Sterile filling unit
- Sterility assurance
- QC expertise
- Validated suppliers
- Quality Assurance
- …

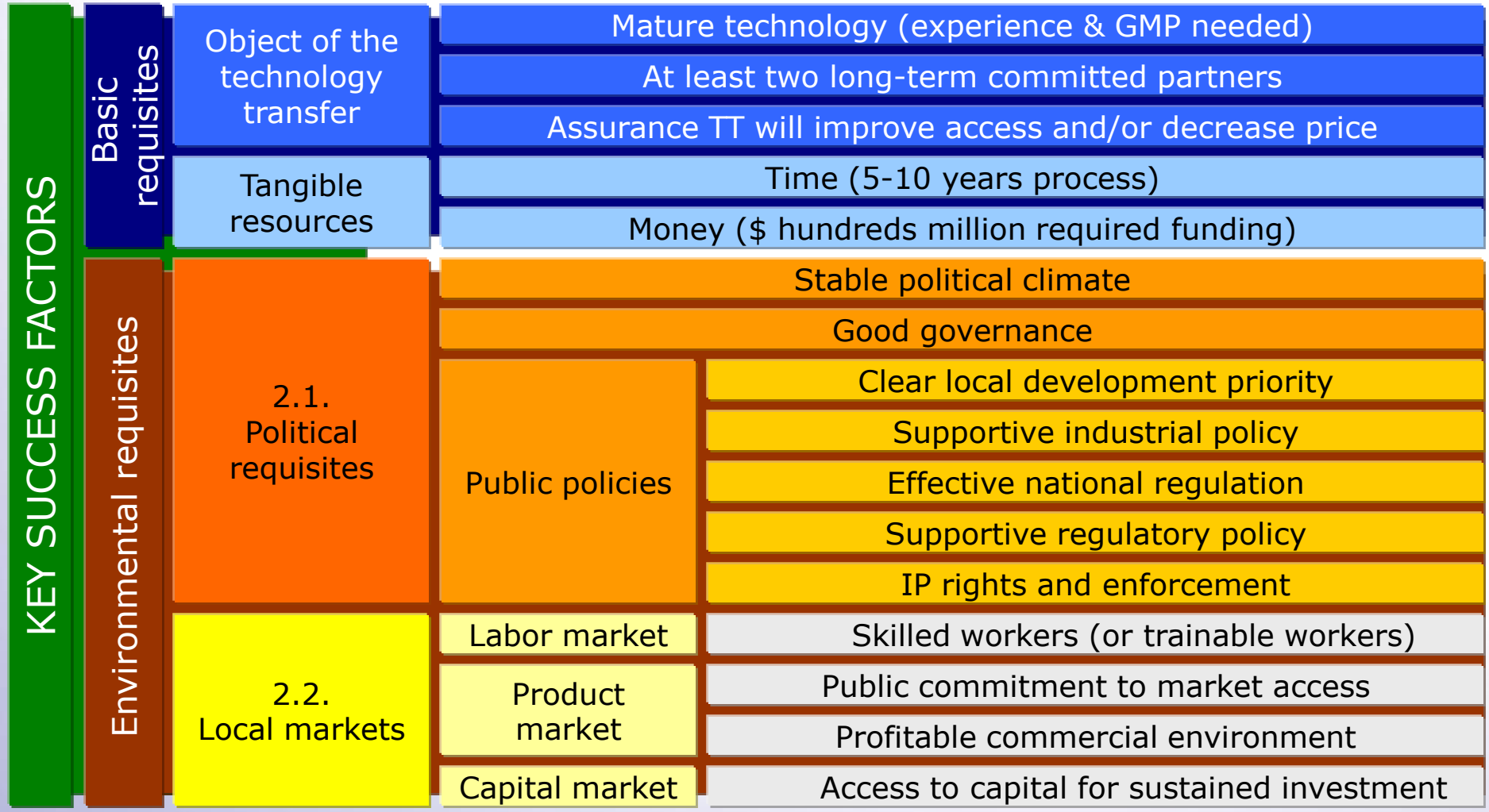
Phase 3

Phase 2 + Production of active principle

Implementation of :

- Engineering
- Bulk production expertise
- Sustainability
- Economic viability
- …

Key success factors for sustainable technology transfer



Conclusion

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- Maintaining a **healthy competitive market** is key to ensure **availability**, **affordability** and **sustainable innovation** of vaccines
- Technology transfer – through **voluntary long-term commitment** of partners – is just one way of building capacity and access – and must be a **"win-win"**, meeting mutual business needs
- The **resources** required for technology transfer programs are **substantial**, and potential **cost of failure** should be factored in
- Technology transfer requires **numerous prerequisites for success**: meeting most - if not all - **enabling conditions**.
- <u>All partners must work collaboratively to put in place such conditions!</u>