Intellectual Property, Vaccine Production and Technology Transfer

Vaccine Industry Perspective

P. Fournier,
On behalf of IFPMA Bio Group

19-20 April 2004, WHO HQ, Geneva
OUTLINE

General considerations on Tech Transfer & Vaccines
  1.1 Patents, Vaccines & Tech Transfer
  1.2 Factors Affecting Access To Vaccines

Tech Transfer Requirements
  2.1 Specific Considerations on Tech Transfer & Vaccines
  2.2 Tech Transfer Challenges

Preconditions for a successful Tech Transfer

Technology Transfer Possible model

Summary
1. GENERAL CONSIDERATIONS ON TECH TRANSFER & VACCINES

- Industry continues to seek innovative ways of ensuring that an adequate supply of safe and effective vaccines is available to help meet the World’s needs.

- Tech Transfer has been suggested as an additional way to help ensure a sufficient supply of vaccines for the World’s needs.

- If Tech Transfer’s main purpose is to facilitate access, initiatives should leverage the vaccine Industry’s long-term commitment in supplying vaccines at low prices to international organizations;
  - The existing practice of tiered-pricing is a powerful tool to help alleviate difficulty in accessing vaccines.
A wide range of health-related technologies can be transferred to developing countries:

- R&D capacity
- Training of personnel
- Clinical trials
- Laboratory testing
- Quality assessment
- Supply chain management and logistical issues
- IT Systems
- Project/HR management
- Production

Local production of biologicals is just one example of technology transfer.

Tech transfer can also help address other fundamental issues

- Development of basic infrastructure/capacity building
- Long term forecasting, etc.
1.1 PATENTS, VACCINES & TECH TRANSFER

Patents have not been shown to be an impediment to access for existing, nor for new vaccines:

- Patents do not prevent competition. There are always alternate routes for the development of new product.
- In many countries, in spite of the availability of affordable non-patented vaccines (e.g. EPI vaccines), coverage is still very poor.

Bottom Line: While patents are generally important to vaccine innovation, they have been shown to have little impact on access to vaccines in developing countries or the likelihood of tech transfer in developing countries.
1. 2 FACTORS AFFECTING ACCESS TO VACCINES

While patents have been shown to have little impact on access to vaccines in developing countries, other fundamental concerns continue to be identified as impediments to access:

- Lack of basic infrastructure (cold chain and other);
- Lack of precise long-term forecasting;
- Financial and logistical hurdles (country willingness and ability to pay);
- Political choices;
- Capacity building;

**Industrial issues:**

- Increased regulatory review times, as well as increasing requirements for compliance with safety and efficacy standards;
- Global variations in regulatory approval requirements;
- Skyrocketing R&D costs;

**Role of tech transfer in addressing these matters is limited**
To be truly viable, a successful Tech transfer must have a very strong rationale based on:

- Two or more willing parties;
- A strong industrial and/or economic value for both parties;
- An adequate level of expertise at the “local producer”;
- It must make sense (i.e. have achievable objectives).

Only a case by case analysis can assess feasibility and chance of success.
2.1 SPECIFIC CONSIDERATIONS ON TECH TRANSFER & VACCINES

- But, by their nature, many tech transfer initiatives pose a number of challenges to the vaccine Industry. In particular, tech transfer for biologicals present a high degree of technical difficulty.

- For this reason, there are few examples of truly successful tech transfer in such areas.

- Even for an experienced vaccine producer, transferring production to another building / site is a real challenge.

- Quality control, and compliance with regulations, are by far the greatest tasks in manufacturing vaccines.
Experience demonstrates that tech transfer can be difficult to complete and can fail to:
- accelerate vaccine availability;
- reduce production costs;
- allow for sustainable production overtime.

Since vaccine manufacture is capital intensive, highly time-consumptive, highly complex, and highly regulated, most related tech transfer is unlikely to result in cost reductions.

Because tech transfer must be GMP compliant, and regulatory validation is lengthy (years), tech transfer is often unlikely to speed up availability.

Tech transfer often requires not only significant initial investment from the local producer (Finance, Quality, expertise, ...), but an ongoing one to achieve sustainability.
3. PRECONDITIONS FOR SUCCESSFUL TECH TRANSFER

- The existence of an independent and competent National Control Authority in the local producer country;
- The existence of consistent GMP conditions at the local producer;
- The existence of sufficiently experienced and trained staff;
- A strong rationale for partnership;
- Assurances of the same vaccine quality from the local producer;
- Guarantees of respect for WTO agreements and intellectual property rights;
- ...
Tech transfer must be considered in a step-by-step approach, in the framework of long-term co-operation, with the mutual interests of the different partners clearly identified, recognized, and respected.

4. TECH TRANSFER MODEL

Phase 1
Packaging and distribution of finished product

Implementation of:
- basis of QC
- Labeling
- Cold chain
- Distribution network
- Adverse event reporting
- ...

Phase 2
Filling of bulk + Phase 1

Implementation of:
- Sterile filling unit
- Sterility assurance
- QC expertise
- Validated suppliers
- QA
- ...

Phase 3
Production of active principle + Phase 2

Implementation of:
- Engineering
- Bulk production expertise
- Economic viability
- ...

...
5. SUMMARY

- It has been suggested that tech transfer could help facilitate access to vaccines to meet global needs.

- There are minimum conditions for consideration of tech transfer which include compliance with GMP standards, existence of a strong and independent National local Control Authority, and respect for current WTO and TRIPs agreements.

- To guarantee success, tech transfer must proceed in phases, in a step by step manner.

- However, there is a low probability that tech transfer will result in less expensive and more innovative products.

- Examples of truly successful tech transfer are rare. Current examples between developed and developing countries include partnerships for DPT combinations.

- Above all, tech transfer must be based on a sound rationale, consider realities of local market and derive good value for all stakeholders.