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REVIEW ARTICLE

COMMERCIALIZATION OF INNOVATIVE PHARMACEUTICAL PRODUCTS-PRACTICAL ASPECTS AND PROBLEMS: AN OVERVIEW

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Abstract:
The process of turning an idea into a marketable product, service, or method is known as commercialization. The most dangerous and costly stage of the technology implementation and product life cycle is commercialization. Commercialization involves testing many ideas and selecting the products that are safer, more effective, and more efficacious than the existing product. Careful justification of practical implementation is very important otherwise problems may occur. Problems in commercialization are usually based on some practical aspects. Problems can also arise in technology selection and strategic planning of technology implementation. This review article briefly discusses the problems in commercialization and gives some ideas on the points to be considered in successful commercialization
Keywords: Technology transfer, Commercialization, Practical aspects, Problems in Commercialization.

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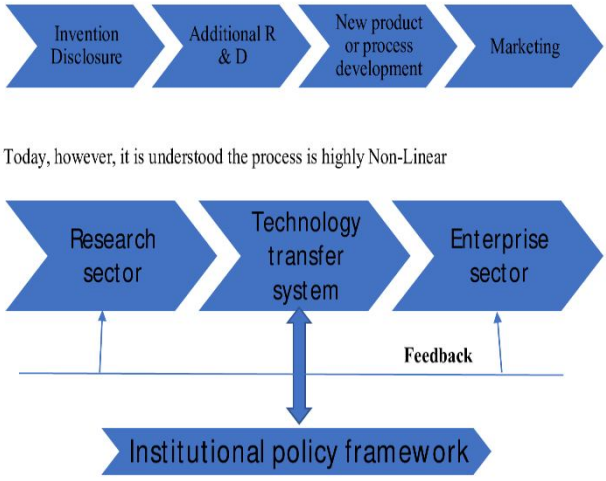
Introduction:

The term "technology transfer" refers to the process of effectively progressing a drug from discovery to product development to clinical trials and finally to large-scale commercialization in the pharmaceutical business. There are three criteria for defining technology: To begin, knowledge must be arranged. This implies that it must be structured in order to provide solutions to issues. Second, knowledge must exist in certain locations, such as in a person's head or in documents, and it must be presentable, which means that it must be transferable from one person to another regardless of its significance. Third, it must be goal-oriented, so that it can be put to good use in industries, agriculture, and business.[1], [2] The process of transfer and commercialization was once thought to be a straightforward one:

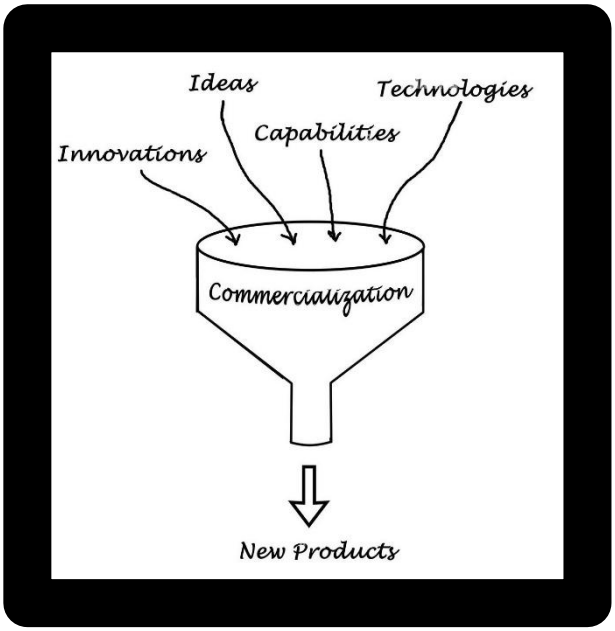


COMMERCIALIZATION:

The process of turning an innovation or creative into a financially viable product, service, or method is known as commercialization. Before the study results can be brought to market, additional R&D, product development, clinical studies, or the development of strategies to boost manufacturing may be required.

-This is significant since not every innovator or creative has the money, expertise, or tolerance for risk necessary to commercialize their own ideas or creations. The process of bringing a new product or manufacturing technique to market is known as commercialization. Many technologies start in the lab and aren't ready for commercial application when they're first developed.[3]

Fig 1: Concept of commercialization.



To make products or technology a viable commercial proposition, the development sector of the research and development spectrum necessitates time and money. The final phase of a new product's development is commercialization, which involves advertising, sales promotion, and other market efforts to promote commercial acceptance of the product technique. Sales, marketing, and company development are sometimes confused with commercialization.[4]

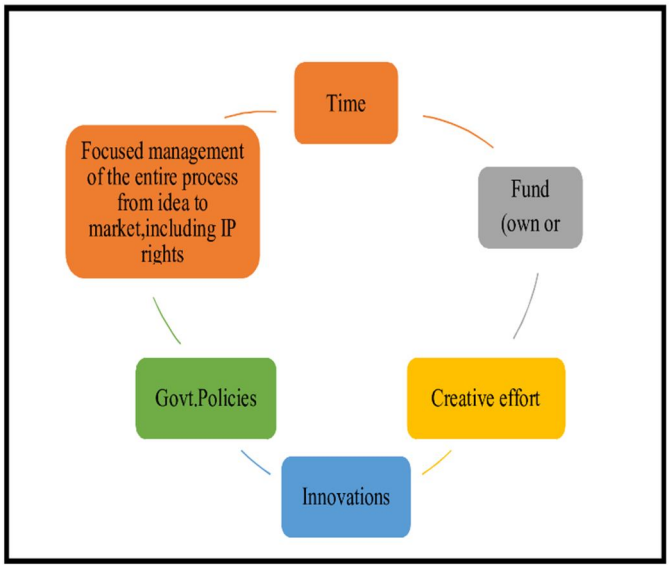
COMMERCIALIZATION-PRACTICAL ASPECTS:

Among the most important aspects of commercialization are

- Commercialization involves testing many ideas and selecting the products that can be safer, more effective, and more efficacious than the existing product.
- Commercialization is a step by step process. Therefore, set goals and milestones for every stage.
- It is important to involve key stakeholders, including customers, early in the process, including customers.

Not all academic institutions or innovative companies have the necessary financial and technical resources necessary to take an invention or creation to market on their own. Resources required Turning an original or new idea, concept or design into a desired product that is available on the market. By improving the technology transfer and commercialisation contextual conditions, countries can increase innovation in the economy and thereby raise productivity, create better job opportunities, and address societal challenges. Not surprisingly, governments have been actively searching for new ways to improve knowledge transfer from PROs to industry. (Rasheed et.al., 2020;Gaurav et.al.,2020)

Fig 2: Practical aspects of commercialization



COMMERCIALIZATION- PROBLEMS:

The creation of innovative chemistry-based goods for the life science sector necessitates the expertise of skilled researchers. These same researchers, on the other hand, are frequently unprepared to address the plethora of other key issues that must be addressed in order for commercialization to be successful. Many early-stage enterprises find that competitors beat them to the punch or that they run out of money before they achieve success because they lack the essential scale-up and commercialization competence. It is critical to carefully justify the practicality; else, issues may occur. [4], [5] Commercialization issues are usually the result of practical considerations, but there may also be issues with technology selection and strategic planning for technology implementation, as described below.

- Scaling production to meet commercial requirements.
- Ensuring that products are compliant with regulations.
- Ensuring adequate funding for product development and manufacturing.
- Protecting intellectual property.
- Issues during the technology justification and selection stage.
- Problems during the planning stage.
- Problems during the negotiation stage.
- Problems during the implementation of the technology.
- Miscellaneous.

1. SCALING MANUFACTURING TO MEET COMMERCIAL REQUIREMENTS

- The early stages of development are usually based on small-scale batch synthesis.
- Thus, drug development is often done virtually to minimize costs.
- The conceptual ideas developed are used to attract additional investment to enable real, but more expensive, development activity.
- On a larger scale, sourcing raw materials and finding suitable and cost-effective manufacturing partners are major challenges.
- Successfully transitioning a technology from the lab bench to the macro level within a commercial production environment is certainly not a trivial undertaking.
- Start-ups must rely on manufacturing facilities that meet the necessary requirements for timeliness, cost efficiency, regulatory compliance, and sometimes geographic proximity.
- If the right production facilities and/or raw material suppliers cannot be found in an efficient manner, irreplaceable time and money will be lost. [3], [5]

2. ENSURING REGULATORY COMPLIANCE

- Pharmaceuticals and other products manufactured for human consumption must comply with government or industry regulations.
- For drugs, these are the FDA's current Good Manufacturing Practices (cGMP).
- For food and nutritional products, food and kosher regulations may apply.
- In the R&D phase, companies can minimize expenses by producing test quantities using non-compliant batch production methods.
- However, converting these methods to regulatory requirements for larger scale commercial production can be extremely time consuming and costly.
- It also often requires a change in equipment, further complicating matters.
- In pharmaceutical manufacturing, for example, cGMP regulations require that all commercially manufactured drugs and pharmaceutical products meet stringent requirements for testing procedures, quality and purity.
- Facilities must have appropriate quality management systems in place to detect, investigate and correct deviations from product quality.
- Submissions of new drug applications (IND) to the FDA can be easily delayed and rejected due to insufficient data, inadequate reporting, or inadequate cGMP reference standards.
- This may require rapid preparation of batches for clinical trials and validation and/or production of GMP-quality material that itself serves as a reference standard.

- The supply of specialized intermediates and precursors for life science applications may require specialized ISO certification at commercial scale.
- This is becoming increasingly important as medical device manufacturers request custom synthesis services for new excipients and components for novel drug-device combinations. [6]

3. SECURING ADEQUATE FUNDING FOR PRODUCT DEVELOPMENT AND MANUFACTURE

- While there are numerous potential sources of finance for product development, fundraising remains competitive, and each investor or funding organisation has its own set of needs.
- Venture capitalists (VCs), angel investor consortia, and government grants such as the Small Business Innovation Research (SBIR) programme given by the National Institutes of Health are all possible funding sources.
- Finding the right grant options for the technology in question and engaging experts with grant writing experience is paramount.
- It is critical for start-up companies to appear before VC and angel boards to promote their new technologies.
- Outside vendors and partners with existing relationships with such funding organizations are attractive options for young companies in need of capital.
- In addition, companies can also license their technology to commercial partners with synergistic or complementary technologies.
- Large pharmaceutical companies typically leverage their resources in this way to strengthen their R&D pipelines.
- However, this requires proof-of-concept work, data collection and analysis to convince potential investors to fund product development activities.
- This is frequently one of the most costly and challenging milestones in the life of a start-up.
- While these start-up often self-confirm a drug candidate's bioactivity, putting together a comprehensive technical package suitable for licensing or transfer is often beyond their capabilities.
- Therefore, it is important for these companies to find external resources capable of synthesis, testing and formulation work at all scales.[7]

4. PROTECTING INTELLECTUAL PROPERTY

Companies must balance the need to avoid patent infringement or protect their own intellectual property (IP) and securely share their confidential process information with development partners. Intellectual property should be matched against existing patents and then protected during development and technology transfer. This is usually done internally by legal staff or by a contracted outside law firm, but any gaps must be filled by additional lab work.

For example, a start-up company must

a. Prepare additional patent example compounds,
b. Quickly synthesize competing samples,
c. Perform analytical measurements to confirm key differences/similarities of target compounds,
d. Identify trace impurities, and
e. Elucidate impurity profiles.

A start-up company needs this work done quickly to maximize future revenues within the limited patent term. [6]

5. PROBLEMS DURING THE TECHNOLOGY JUSTIFICATION AND SELECTION STAIR:

Some problems with commercialization may arise from incorrect selection of technology and if the selected technology is complicated to understand and implement.

The cost of acquisition, installation, maintenance, and operation are also considered when selecting the technology. If the costs are very high or if an abrupt increase in any of the above costs causes financial planning problems, a monetary fund is required. An important point

is that the technology is not adapted to local conditions, as further technologies require extensive adaptation.[10]

6. PROBLEMS DURING THE PLANNING STAIR:

Planning is the foundation of successful management. Both SU and RUs are responsible for planning, forecasting and implementation. Some problems in planning and implementation of planning lead to commercialization of some points to be considered in planning. SU should fully understand the needs of the RU. The manager of the RU should be involved in transfer planning. Software or intellectual needs are given more attention. Special effort in market forecasting. RU and SU goals should be clear. The chosen mechanism for implementing the technology in the RU should be appropriate.[8]

7. PROBLEMS DURING NEGOTIATION:

RU and SU seem to have complementary rather than competing technologies and are eager to expand their product range, which probably leads to a better mutual understanding, but also to some problems in negotiations, such as lack of trust or different approaches or strategies in negotiations. The technological and commercial value of intellectual property should be assessed at a very early stage so that successful commercialisation can take place. If it is difficult to reach agreements on the intellectual property rights and the price of the technology, commercialisation may be delayed.[8]

8. PROBLEMS DURING TECHNOLOGY IMPLEMENTATION:

Successful technology implementation involves some aspects like skilled manpower, financial resources and material quality. Mismanagement or lack of planning in these aspects leads to problems in commercialization. The following examples lead to problems in technology implementation and eventually commercialization, Lack of resources such as: Technical staff, equipment, supporting staff, premises and equipment, financial resources. Inability to achieve goals. Lack of funds and cost overruns due to poor implementation, Delay or mismanagement of the demand and supply chain. High cost or poor quality of locally available materials needed to implement the technology.[5]

9. MISCELLANEOUS:

The various problems include lack of skilled labour, incomplete process validation, high batch rejection rate, shortage of manpower and labour, and incomplete documentation which can lead to problems in marketing.

COMMERCIALIZATION: SOLUTIONS TO PROBLEMS

In the commercialization of technologies, sales promotion includes a range of advertising techniques used to attract the attention of intermediaries or end users to the product or services. It helps to promote the sale of a product during the introduction and maturity stages of the product life cycle. Therefore, all pharmaceutical industries use this technique at one or the other stage of the product life cycle. This technique also helps the company to get maximum profit from its product and thereby increase the business standard and grow the business. Apart from personal selling and advertising, sales promotion also includes other activities like distribution of free samples, demonstrations, discounts, window displays, trade fairs and exhibitions etc. In all these processes, pharmaceutical sales representatives play an important role in personal selling as it is an important method of pharmaceutical sales promotion. He can increase the awareness and interest of the doctors and convince them to prescribe the product to the end user. Distribution of free samples is the fastest and best way to introduce a new product in the market.

Conclusion:

The success of technology implementation is reflected in commercialization. It is more and most expensive stage because sales are low,

demand for the product is low, and distribution is limited. This includes some practical aspects such as innovations, government policies, financial resources (IPR), skilled and trained employees, proper management of the whole process and many more. Some mismanagement of practical aspects leads to problems in commercialization process. We discussed in brief about the problems of commercialization. Which gives some ideas about the points to be considered during successful commercialization.

Reference:

[1] D. Thompson, "Tech Transfer and Commercialisation," no. May, p. 142, 2015.

[2] R. Wani, A. M. Kashid, A. B. Ghathe, and S. G. Shaoo, "An Overview of Technology Transfer in industry," *Int. J. Adv. Pharm.*, vol. 06, no. 06, pp. 103–109, 2017.

[3] P. Srivastava and S. Chandra, "Technology commercialization: Indian university perspective," *J. Technol. Manag. Innov.*, vol. 7, no. 4, pp. 121–131, 2012, doi: 10.4067/S0718-27242012000400010.

[4] D. Discovery *et al.*, "Quick response code," vol. 4, no. 5, pp. 1692–1708, 2013.

[5] G. J. Brewer, "Fundamental problems lie ahead in the drug discovery and commercialization process: Restructuring of the pharmaceutical industry and an improved partnership with academia are required," *J. Investig. Med.*, vol. 54, no. 6, pp. 291–302, 2006, doi: 10.2310/6650.2006.05030.

[6] H. N. Su and Y. S. Lin, "How do patent-based measures inform product commercialization? —The case of the United States pharmaceutical industry," *J. Eng. Technol. Manag. - JET-M*, vol. 50, no. July 2017, pp. 24–38, 2018, doi: 10.1016/j.jengtecman.2018.08.002.

[7] R. R. Ahmed and J. Vveinhardt, "Product Development & Commercialization in Pharmaceutical Industry," *Pharma Innov.* , vol. 3, no. 9, pp. 41–46, 2014, [Online]. Available: http://thepharmajournal.com/vol3Issue9/Issue_nov_2014/9.1.pdf.

[8] M. Bianchi, D. Chiaroni, V. Chiesa, and F. Frattini, "Organizing for external technology commercialization: Evidence from a multiple case study in the pharmaceutical industry," *R D Manag.*, vol. 41, no. 2, pp. 120–137, 2011, doi: 10.1111/j.1467-9310.2010.00632.x.

[9] Dr. Shaikh H. Rasheed, (2020) A textbook of Industrial Pharmacy –II. *Sia Publishers and Distributers Pvt. Ltd.* (chapter: II-2.18).

[10] Gaurav Agarwal, Jyoti Ghangas, (2020) Industrial Pharmacy –II, *CBS Publishers and Distributers Pvt.Ltd.* (chapter: 6-87).