PHARMA SCIENTISTS REFLECTION ON R&D IN NEPALESE PHARMACEUTICALS: A QUALITATIVE STUDY

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Abstract

Pharmaceutical companies are greatly regulated and monitored by both the government and the public. R&D is mandatory, core, and plays a significant role in the pharmaceutical industry. Considering this aspect, a qualitative study is done taking information from eleven key pharma scientists from four different pharmaceutical companies. The key participants for this study were Nepalese pharmaceutical scientists who were engaged in the R & D department. In addition to this, the expertise of quality control, quality assurance, production, and pharmaceuticals leaders specific to pharma executives were also taken into consideration. The study findings are categorized into four themes consisting of R&D challenges, factors influencing R&D, R&D spending, and financial aspects. The study results showed that higher investment for R&D, the complexity of clinical trials, administrative issues in the governing body, low output in research, and reduced R&D efficiency of pharmaceuticals company are the key R&D concern where the expected costs to develop a new drug, anticipated lifetime revenues from a new drug, and policies and programs that influence the supply of and demand for prescription drugs are the factors influencing R&D.

The study concluded that the portion of the pharmaceutical industry requires innovation, investment, and intelligence for the expected level of research and development. Further, R&D is not as such R&D in Nepalese pharmaceuticals as the true amount of investment is still the prime concern for exploiting the effective rate of return from drug manufacturing.

Key Words: R&D, qualitative research, pharmaceutical investment, profitability

I. Introduction

Pharmaceutical companies are greatly regulated and monitored by both the government and the public (Jirasek, 2017). R&D is the core (Kim, 2014) and plays a significant role in the pharmaceutical industry (Erickson & Jacobson, 1992). It has a noteworthy effect on gaining superior performance (Ho et al., 2005). For instance, Bhagat et al. (2001) study reported that an increase in R&D investment leads to increased EPS (earning per share) of pharmaceutical companies. Similarly, research-based pharmaceuticals have a high portion of R&D intensity (Tjandrawinata & Simanjuntak, 2012). The realized importance of research and development (R&D) for the introduction of new products especially in Nepalese pharmaceuticals is the central issue of the study. The question of highly capital-intensive, effort to introduce and the expertise of existing human resources, called pharma scientists and their availability in Nepalese pharmaceuticals is another focus of the study.

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The concept behind R&D in pharmaceuticals states that pharmaceutical companies develop and produce drugs for relieving diseases. The most noteworthy actions in the industry consist of medicine development, production of the active pharmaceutical ingredient called primary production, and production of the drug distribution system, e.g., vials or pills called secondary production. It's obvious that evolving and introducing a new medicine incurs a substantial amount of phase and money, since new drugs have to go through a series of clinical trials prescribed by regulatory authorities based on the prescribed standard. These trials involve testing the medicine on a large number of patients and intensive care their response to the medicine while using other patients given a placebo as a reference group. The trials should show not only the efficacy of the medicine but also find possible side effects and the pharmacokinetic properties of the drug.

Each country has its authority, which needs to approve the medicine, such as DDA in Nepal, and FDA in the US. Based on the established guidelines, pharmaceutical companies attempt to get the medicine approved in one country and thereafter use mutual recognition for getting the approval in other countries or the company can just get it approved in each country (Davis, 2003). Common for all authorities in all countries is that they need to approve the drug before it can be sold in the respective countries.

In Nepal, the most influential regulatory body is the DDA. This authority puts up Medicine Registration Guidance (DDA, 2016) and Drugs Registration Rules, 2038 for how pharmaceutical companies in Nepal should behave. Most noteworthy are the prescribed clinical trials, which require companies to test their medicine on a sizable population in a controlled manner such that the proven efficacy of the drug and any possible side effects are discovered. In the context of Nepalese pharmaceutical companies, DDA has made it mandatory to have all pharmaceutical companies own R&D departments and comply with the process for product registration as per WHO-GMP guidelines and pharmacopeia standards (DDA, 2016). However, no evidence was found introducing new products of their own in Nepal. A research-based pharmaceutical company is still not yet evident.

Thus, this study is highly motivated to present the status of R&D and its development in the Nepalese context connecting with the reflection from scientists who devoted their work for R&D in Nepalese pharmaceuticals.

II. Literature Review

Pharmaceuticals' history is fundamentally backed by the mythological origin of Ayurveda and has a strong link with Brahma, the God of Creation. "Ayurveda originated in the 10th century BC, but its current form took shape between the 5th century BC and the 5th century AD. In Sanskrit, Ayurveda means 'science of life"(WHO, 2001, p. 12). Khakurel (1996) mentioned in his presentation that Nepalese people use medicinal herbs before 500 AD. Similarly, "Allopathic medicine refers to the broad category of medical practice that is sometimes called, Western medicine, biomedicine and scientific medicine (or, modern medicine)" (WHO, 2001, p. 11).

Ayurveda has been a national medical system in Nepal (Kunwar & Leboa, 2017). Ayurveda is referred to as the "Mother of all healing". Pharmaphorum (2020) also mentioned, "origins of the pharmaceutical industry lie back with the apothecaries and pharmacies that offered traditional remedies as far back as the Middle Ages, offering a hit-and-miss range of treatments based on

centuries of folk knowledge". R&D of pharmaceutical products is necessarily a lengthy process (Elmquist & Segrestin, 2007, as cited in Kim, 2014).

In response to the importance of innovation in pharmaceuticals, the (WHO, 2002, as cited in IFPMA, 2004) reported that:

> "*Out of more than 5,000 identified diseases, the number of disease genes discovered so far is 1,253 and the molecular characterization of clinical disorders exists for more than 1,700 diseases. Even for those diseases with a relationship to disease genes, the molecular sequences needed to design a drug are largely unknown. That leaves a significant number of medical conditions whose origins are unknown and which consequently lack appropriate treatments*" (p. 13).

CBO (2021) claimed that the pharmaceutical industry devoted $83 billion to R&D expenditures in 2019 for discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. Similarly, CBO (2021) stated three factors of R&D spending in pharmaceutical companies namely "anticipated lifetime global revenues from a new drug, expected costs to develop a new drug, and policies and programs that influence the supply of and demand for prescription drugs"(p. 5).

Developing a new medicine is a long process in pharmaceuticals, as it is subject to many strict requirements or guidelines called Good Manufacturing Practices (GMP) issued by the Food and Drug Administration (U.S. Food and Drug Administration, 2021). The harder requirements set by the regulatory authorities for proving better efficacy than existing treatments (DiMasi and Grabowski, 2007) to safeguard patients by putting high demands on quality and cleaning to avoid (cross) contamination in production (Grunow et al., 2003) take longer and are less likely to return a sellable drug afterward (DiMasi, 2002). It is evident that out of 10,000 compounds screened, 250 enter pre-clinical trials and 1 drug eventually reaches the market (PhRMA, 2012). Thus, R&D pipelines are no longer thriving with an abundance of potential blockbuster drugs (Hunt et al., 2011). As generic manufacturers launch cheap copies after patent expiration, companies have to be good at developing their drugs fast, if they want to use the exclusivity of the patent protection for recouping their investment and turning a profit.

Lee and Choi's (2015) study of Korean pharmaceutical companies showed that investment in R&D is determined by liquidity rather than return on investment or sales growth of the company.

III. Research Methods

The study followed a grounded theory approach (Martin & Turner, 1986) in which qualitative data was obtained from direct interactions with pharma scientists while seeking research and development in the pharmaceutical company. Based on Yin (2016), this study believes that qualitative inquiry in R&D can assist in the appropriate contribution to pharmaceutical decision-making. The interview information is envisioned to present the results found in the discussion by availing a more thoughtful view of the phenomenon associated with R&D investment. Pharmaceutical scientists were purposively chosen. The key participants for this study were Nepalese pharmaceutical scientists who were engaged in the R & D department. In addition to this, the expertise of quality control, quality assurance, production, and pharmaceuticals leaders specific to pharma executives were also taken into consideration.

Table 1 Demographic characteristics of participants in the study (N=11)

	Interview Participants		***Interview Participants***
Age Group		*Education*	
25-35	*3*	*Graduate*	*8*
35-45	*5*	*Doctoral*	*3*
45>	*3*	*Experience (years)*	
Marital Status		*5 to 10*	*5*
Single	*5*	*11 to 20*	*4*
Married	*6*	*20>*	*2*

IV. Data Collection

During obtaining data relevant to pharmaceutical scientists' opinions, enough opportunities were provided to the respondents to share their opinions. Individual interviews with eleven pharma scientists were taken around 10 to 20 minutes each. Research participants were given comfortable time to deliver their opinion relevant to R&D issues, investment, and related areas. The researcher pretended to be an active listener (Yen, 2016) to gain more insights into the title. Participants were encouraged to add more and more remarks on the pertinent issues of the topic. The conversations were transcribed and also copied free opinions based via message box. After getting back all the information, the data were coded and then categorized into four themes R&D challenges, factors influencing spending for R&D, R&D spending, and financial aspect. In the findings section, data obtained from the interview are presented.

V. Ethics

Since, this study is purely qualitative in nature, reliability, basically strives on the stability of pharma scientists' reflection towards R&D among eleven responses which have been keenly analyzed using data code, categorizing the data into four separate themes and also thematizing the data to validate the core idea under study. The study used the reference from Lincoln and Guba's (1985) study for the right "trustworthiness" equivalent for internal validation, external validation, reliability, and objectivity. Similarly, for internal consistency, the reference from Creswell and Poth (2013) was also considered for assessing the "accuracy" of the information.

In this study, pharma executive heads were interviewed; however, their opinions are cross-matched with the pharma scientists working in R&D. This is a way of assuring the validity of research to cross-validate information and capture a different dimension of the four themes of this study. Data during the interaction session were typed and written statements via message box have been directly copied and pasted to the data sheet by the primary researchers. Based on the statements, key notes/points/themes were coded and sorted into categories, then arranged into themes using cross-sectional thematic analysis by the primary researcher. The process of categorizing the data and the formation of themes was cross-checked. This process elicited primary and secondary themes very closely aligned with those formed by the researcher. From the themes, unifying constructs were identified.

VI. Research Findings

The finding of this study is categorized as per the key themes of the study consisting of R & D challenges, factors influencing R&D, R&D spending, and financial aspect. The following section consists of a detailed discussion of how the five dimensions of R&D in pharmaceuticals.

R&D Concern

R&D concern in the Nepalese pharmaceuticals industry is vital as opined by the majority of the respondents during the interaction phase of data collection. They also opined that there exist numerous challenges in R&D such as a higher burden of approval, complex research required for new drugs, higher capitalized cost for R&D, the complexity of clinical trials, lower risk tolerance of regulators, and society, low output in research and reduced R&D efficiency of Pharmaceuticals Company.

Factors influence spending for R&D

During the discussion relevant to reflection on R&D, frequent statements were under discussion on factors influencing R&D in Nepalese pharmaceuticals. Based on this, key factors were outlined as the expected costs to develop a new drug, anticipated lifetime revenues from a new drug, and policies and programs that influence the supply of and demand for prescription drugs.

R&D Spending in the pharmaceuticals

While interacting repeatedly with the research participants relevant to factors that influence R&D, the repetitive nature of R&D spending statements was underlined such as:

- *Invention, or research and discovery of new drugs*
    - o *Development, or clinical testing, preparation and*
    - o *submission of applications for DDA approval, and*
    - o *design of production processes for new drugs*
- *Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications*
- *Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior*

Financial aspect

The research participants considered the financial aspect as the key part of pharmaceuticals R&D. One of the pharmaceuticals scientists' perceptions about the financial aspect as per his experience:

> *Initially, the investment in R&D labs with laboratory equipment is very high for Nepalese pharmaceutical investors. Secondly, the sourcing of raw materials for R & D seemed higher due to the high rate for small quantities and the high rate for courier charges. Raw materials sourced from third countries like Germany, England, … incur high rates. The cost for reference standards, frequent trials, and hiring experts for the product introduction are very high, and management, sometimes felt, a delay in decision-making due to the high amount of investment.*

The key financial indicators have been directly associated with the R&D investment as perceived by the respondents. Among the financial indicators, the most repetitive indicators perceived by the respondents in connection with R&D aspects are:

· Inventory of R&D specific to raw materials, reference standards, and quality testing competency has a positive influence on R&D

- Easy and subsidized bank financing for R&D materials has a positive influence on R&D investment
- Expected return on investment has a positive influence on R&D
- The expected increase in sales has a positive influence on R&D

Existing status of R&D

Pharmaceutical companies' major requirement is having their R&D lab. During the interaction with pharma scientists, they claimed that a few companies were having R&D activities in their lab but few of them were in the quality control lab. The opinion and actual aspect of R&D was found contradictory in the sense of necessity and requirements. Dr. Duganath, relevant to the context of the existing status of R&D in Nepalese pharmaceuticals companies stated:

> *Few companies are found investing a huge portion around more than 10% of the total investment in R&D departments including plants, machinery, system, people, raw materials trials, and people. Rabbits and rats were also used to test the efficacy of the products which was a good practice in R&D trials.*

VII. Discussion

The above explanation shows that the research and development in the Pharmaceuticals Company in Nepal are influenced by financial indicators such as current ratio, debt, return on investment, and sales growth (Lee & Choi, 2015; Pokharel, 2017; Pokharel, 2018; Pokharel, 2019). Specifically, investment in laboratories, quality control, retaining pharmaceutical scientists with a comfortable working environment, and the expected level of return on investment in R&D have given great attention to Nepalese pharmaceutical investors.

VIII. Conclusion

It can be concluded that a portion of the pharmaceutical industry requires innovation, investment, and intelligence for the expected level of research and development. R&D is not as such R&D in Nepalese pharmaceuticals as the true amount of investment is still the prime concern for exploiting the effective rate of return from drug manufacturing.

Although the attempt of introducing new products in the companies is made, it is necessary to update to the tune of R&D-based pharmaceutical companies having an adequate number of pharmaceuticals of research, comfortable quality control laboratories, the right number of pharmaceuticals scientists, and visionary investors.

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