The Evaluation of Research and Development Division through Product Development Process in Biopharmaceutical Company

E S Hariandja
Universitas Pelita Harapan, Business School-Department of Management, Tangerang 15811, Banten, Indonesia

evo.hariandja@uph.edu

Abstract. This study aims to offer the methodology and analyze the performance of Research and Development division of the most significant biopharmaceutical company in Indonesia through improvement of new product development (NPD) process. The methods in this study using the combination of the survey through a questionnaire that already created and modified according to the biopharmaceutical sector in Indonesia and interviews with the principal persons in the company. The respondents are manager level in the various departments such as R&D, product planning, product development and supply chain management. The results stated that R&D has a significant role in providing and determining the new product and must be emphasized as corporate level action. The solutions that offered to the company are conducting organizational development through training & development and collaborative partnership that require world-class skills and knowledge.

1. Introduction
Health investment plays a vital role in economic development. At the micro level (level) for example individual and family, health is the basis for work productivity. A healthy workforce will have an impact on the quality of the work produced. At the macro level, people with good health are essential inputs for reducing poverty, economic growth and long-term development [1]. Health has a compelling economic role in human resources and corporate capital. Poor health will adversely affect economic growth. One indication of poor health is the spread of infectious diseases that become a health burden in the community to this day. It has a direct connection with the pharmaceutical industry by making various efforts such as treatment interventions and promotional and preventive efforts. One of the preventive measures is immunization [2].

With vaccination to make the pharmaceutical business proliferate. In the 21st century, vaccines have become one of the essential public health factors in disease prevention and treatment. In the next 5-15 years, new vaccines and technology will be the basis for the prevention and treatment of various diseases that affect public health. The prospect of prevention and treatment of severe illnesses using predicted vaccines is an exciting development in public health [3]. The pharmaceutical industry is a research-based industry that requires continuous product innovation, costly promotion, good marketing organizations, strict product arrangements at the local and international levels, primarily by WHO [4].

PT. Bio Farma is an internationally recognized local pharmaceutical company WHO engaged in the manufacture of vaccines and sera. Currently, PT. Bio Farma feels the weight of competition in the
pharmaceutical industry with the emergence of outside competitors with better technology. For that
needed a strategic step to encourage the progress of the company regarding product innovation [5].

Based on the above background, Bio Farma must have a robust strategy to be able to grow and adapt
to the complexity and changes that occur. One step that needs to be taken to answer the challenge is to
make improvements in product development to compete with competitors so that Bio Farma will be able
to utilize the potential of information and knowledge available based on current and future market needs.
From the background that has been described, some things concern the new product development
process that is the benefits of new product development and risk of failure. The cause may come from
internal and external companies. One of the causes of such failure is resource constraints.

The formulation and limitations of the problem in this research refer to the following: 1) How the
stages of new product development in PT. Bio Farma?, 2) What causes problems in new product
development?, 3) How are the remedial measures to be taken?. For discussion in this research have clear
direction and purpose, hence need to do problem restriction that is: 1) Discussion of new product
development process refers to R&D performance, 2) Resources are human and infrastructure and 3)
Product focused on a vaccine which is a mainstay.

2. Conceptual framework
In this study, the initial idea is to create a new vaccine for Bio Farma to compete with its competitors.
This is influenced by several factors as shown in Figure 1 below:

![Conceptual framework](image)

**Figure 1.** Conceptual framework.

3. Methodology
The methodology in this study using the questionnaires and face to face interview with manager level
in the department of product planning, research, and development, product development, marketing and
supply chain management. The problem-solving method can be seen in Figure 2 below:
3.1. NPD stages

Stages in new product development adjust to company conditions. According to [6] and [7], the stages of the new product development process as shown in Figure 3 and Figure 4 below:

Figure 3. Ulrich and Eppinger NPD process.

Figure 4. Donald and Winer NPD process.

The Ulrich-Eppinger NPD process is well-known as the generic product development process. In biopharmaceutical companies, the testing and refinement play the central role to make sure that the final products are safe for the customers. So that, the process of testing and refinement becomes the critical part of the product development process. In Figure 4, the product development process that was proposed by [7], combines the technical, marketing and business aspect into the NPD process. The aspect of the product development must align with corporate strategy and the business aspect beside the
technical. In NPD process of PT. Bio Farma, marketing, and strategy aspect will be considered as an essential part.

3.2. Characteristics of the vaccine industry
The biological products industry is based on science and technology. Therefore very sensitive to the development and progress in the field of science and technology. Discoveries in the field of genetic engineering in biological products will bring a considerable change in production technology and immunization programs. This program is estimated that in the next five years a combination vaccine will be needed. The biggest buyers of vaccine and sera products in Indonesia are the government. These characteristics of vaccine industry as follows: productive research, new vaccines, growth, and investment in intellectual assets.

4. Results and discussion
Based on the interviews, the new product development strategy is as follows: 1) Product innovation, 2) Improving laboratory quality control laboratory through enhancing human resources skill, 3) Cooperation with international institution as the owner of technology such as NVI, GCVC, etc. and 4) Providing adequate R&D facilities that comply with WHO qualification standards for new products.

New product development strategy at PT. Bio Farma is done to gain the competitive advantage of the company. Although nearly 50% of new products launched on the market each year fail, companies will continue to explore innovations to produce successful products in the market. The new product developed by Bio Farma is a non-derivative product such as a product to cope with diseases: polio, tuberculosis, malaria, leprosy, ISPA / pneumonia, HIV / AIDS, DHF & Bird Flu, Diarrhea. Bio Farma is one of the worlds of 21 vaccine manufacturers supplying local and global markets. Currently Bio Farma able to increase market penetration and has reached to 100 destination countries [2, 5].

4.1. NPD process of bio farma
The development of new products is significant to maintain the long-term existence of the company. The new product developed by Bio Farma is the result of the policy with the government. In new product development requires priority for planning effectively and efficiently. Determining the priority is seen from the number of development costs, market demand, profit predictions to be gained, and product development time. Marketing departments usually see the market needs and prospects of the product when launched into the market. Here are the stages of new product development process at PT. Bio Farma as shown in Figure 5 below:

![Figure 5. Bio farma NPD process.](image-url)
Based on the above process flow, it appears that the manufacture of new products based on demand from customers such as private companies and the government. The private companies such as pharmaceutical and medical center request the vaccines to PT. Bio Farma after gaining the approval from Ministry of Health as government. The government makes a policy of what products will be made based on market demand. Usually, new products are issued to see the disease that is happening in the community. The marketing department estimates sales, priorities, and benefits. If the new product predictions are profitable, a design plan will be made to make the product. The R&D department will accept and execute new product development requests according to the time scheduled by the management company. This stage takes a long time and costs a lot.

The R&D role in seeking and discovering the new vaccine through the basic and applied research by using the local and import material. If the research phase has been done, then the next process is a production that is directly supervised by the Department of QC. The production is done to meet WHO standards and customer satisfaction. In R&D and production processes, the procurement of raw materials and tools plays an essential role in the continuity of the product development process. After that done, the distribution to be used as a clinical trial through a survey about the effectiveness of the resulting product. Figure 6 shows the process of developing a vaccine product.

![Figure 6. Bio farma vaccine NPD process.](image)

From Figure 6 above, it can be seen that it takes 12 years to create a new vaccine. The Bio Farma NPD process has a different level of difficulty and the number of sub-processes that must go on. Currently, Bio Farma is developing new vaccines such as Rotavirus, Thypoid Vi, Cholera, Hib, Td, Seasonal Influenza and Sabin IPV. The vaccines are currently in the process of the experimental lot, clinical development, and commercial manufacturing. In the development of vaccines, the process through which each vaccine varies, some of which start from applied research and there is starting from clinical development. Based on interviews with parties related to the development of new products, it is obtained information that some problems become obstacles in developing a new product. Namely: 1) Rapid technology development, 2) New product development time, 3) The amount of new product development fund, 4) The existence of cooperation clause, 5) Limitations of R&D personnel, 6) Reduced coordination between personnel, and 7) Limitations of facilities for R&D.

There are several alternative solutions to overcome the problems that occur in the process of developing new products in PT Bio Farma. Alternative solutions will be explained as follows: 1) Organizational Development: coordination between personnel to improve integration between personnel skill and knowledge. Organization development can be done with a variety of methods such as action research, collaborative in solving a problem, knowledge management, team building and training and development. All activities intended to improve performance, skills, and knowledge. 2) Collaboration and Integration with national and international institutions in the development of new vaccines. 3) Streamline every process performed. 4) Establish good relationships with suppliers. 5) Promote collaboration with pharmaceutical industries in Indonesia.
5. Conclusions
Based on the analysis of new product development process in PT. Bio Farma, then the best solution is organizational development through collaborative action, training, and development. The collaborative action regarding mutual basic and applied research with a various domestic pharmaceutical such as Sanbe, Kimia Farma, Kalbe Farma, Dexa Medica. The collaboration between PT. Bio Farma and international pharmaceutical like Pfizer, Johnson & Johnson, Merck, still under process. This collaboration to make new products conduct a company level action. Collaborative action consisting of processes, behaviors, and conversations related to inter-personnel collaboration.

Through training & development will improve the company's human resources. This opportunity is given to personnel directly involved with the development project. The specific topic of training and development such as GMP (Good Manufacturing Process), ISO 9000, Quality Control, Marketing Strategy, Budgeting and Costing, Financial Planning.

References
[1] R Strategis dan Kesehatan 2015 Kementerian Kesehatan Republik Indonesia p. 248.
[2] Suhardono M, Ugiyadi D, Nurnaeni I and Emelia I 2011 “Establishment of pandemic influenza vaccine production capacity at Bio Farma, Indonesia,” Vaccine 29 (1).
[3] Nur K, Pangest A and Setiawaty V 2014 “Masa Depan Vaksin Rotavirus di Indonesia,” Media Litbang Kesehat. 24 215–220.
[4] Dirjen POM RI 2009 Farmakope Indonesia edisi IV.
[5] Hariandja E S and Pratomo L C 2017 “New product development strategy of stem cell-related products in Indonesia biopharmaceutical industry,” in Proceedings of the International Conference on Industrial Engineering and Operations Management.
[6] Ulrich K T and Eppinger S D 2012 Product Design and Development 5.
[7] Lehmann D R and Winer R S 2004 “Product Management,” Eur. J. Mark. 21 (6) 318–57.