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PRODUCT REGISTRATION STRATEGIES

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Abstract:
The case organization Vaisala was interested in finding out whether there was a need for a product registration that would attract customers. More specifically, the elements of added value were under the scope of this development work. The work was framed so that only the end-users of the company's flagship product was under the scope. The initial idea came from the company's Customer Experience Program which set the objectives for a product registration study.
The development work followed the principles of service design and its process model called Double Diamond which gave structure to the work. Various service design methods and tools were used along the process such as benchmarking, theme interviews, Affinity Diagram tool, How Might We? tool, customer personas and customer journey map. The ideation session provided the relevant ideas for prototyping. The final prototype summarized the whole development work into practical concept of a portal.
The order of this development work was first to investigate organization's operating environment, the product management and stakeholders involved in the project in order to have better understanding of the matter. The theoretical framework addressed the themes of value proposition, value co-creation, customer experience, customer journey and customer engagement. This theory basis provided understanding for what elements are needed when developing service concept for customers.
As a result, a prototype of a portal with value-added elements was created. The prototype includes features and functions which support customers in their internal processes by improving their communication and knowledge sharing. The outcome is an asset management tool for customers that enables case organization to support customers even better.

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INTRODUCTION:

Harmonization of regulatory requirements for registering new medicinal products began in the 1970s as the European Community (now the European Union, EU) moved toward develop- ing a single market for pharmaceutical products. European guidelines were developed by the Committee for Proprietary Medicinal Products (CPMP) and its scientific working parties. At the same time, there were bilateral discussions between Europe and the United States (U.S.A.) on the one hand and Europe and Japan on the other on the possibilities of harmonizing data requirements for registration files for pharmaceutical medicinal products. In 1989, the phar- maceutical industry proposed that a joint industry-regulatory authority initiative be set up to harmonize requirements for safety, quality, and efficacy. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was set up in 1990. Its objective is to ensure that good quality, safe and effective medicines are developed and registered in the most cost-effective and efficient way.

The "players" in ICH are the regulatory agencies and the research-based industry in the three ICH regions of Europe, Japan, and the United States. They comprise the Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) for the United States, the European Commission/European Union and the Euro- pean Federation of Pharmaceutical Industries and Associations (EFPIA) for Europe, and the Ministry of Health, Labour and Welfare (MHLW) and the Japan Pharmaceutical Manufactur- ers Association (JPMA) for Japan. There are observers at meetings of the ICH from the World Health Organization (WHO), the European Free Trade Area (EFTA) (currently represented by Swissmedic), and Health Canada.

The ICH is managed by its Steering Committee, which meets twice yearly. Topics for harmonization agreed by the Steering Committee are considered by Expert Working Groups (EWGs), which meet in parallel with the Steering Committee to discuss scientific and technical aspects. The EWGs recommend texts of guidelines to the Steering Committee for issue for consultation and then for adoption.

WORK ON THE COMMON TECHNICAL DOCUMENT

The first topics considered for harmonization are related to safety, quality, and efficacy. The topics chosen were those where there were significant regional differences between the regulatory requirements, which added to the costs for developing of new drug products. After this first period of harmonization of key regulatory requirements, the ICH turned its attention to the format for documentation in a registration file. The objective was to remove redundancy and duplication so that as far as possible a single set of data could be provided to demonstrate safety, quality, and efficacy. The aim was also to reduce the delays and costs involved in converting registration files between the different national formats.

Adoption and Implementation of the CTD

The final text of the CTD was issued in November 2000 by the ICH Steering Committee and this has now been revised and updated (1–4). The CTD was implemented as an optional format in the European Union, the United States, Japan, Canada, and Switzerland. It became mandatory from July 2003 in the European Union, Japan, Canada, and Switzerland. It is the recommended format in the United States as ICH documents have always been considered as guidance by the FDA, and the September 2000 Good Guidances Practice Final Rule requires that the CTD not be mandatory.

The CTD format has also been adopted in Australia by the Therapeutic Goods Admin- istration (TGA) and it became the mandatory format after June 30, 2004. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) announced that the CTD format became mandatory for all intermediate-risk and high-risk new medicine applications from September 1, 2006.

AIM AND OBJECTIVE

The aim of this development work was to identify the need and added value of product registration for end-users, and the optimal registration process that would benefit them. The product registration would also enable the organization to collect customer data and improve its services and processes.

DISCUSSION

Biomedical materials are a group of special functional materials that aid in the diagnosis, treatment, recovery or replacement of diseased or damaged tissues or organs, and promoting functions of physiological systems. The use of medical materials not only saves the lives of many patients and significantly decreases the death rate of patients with various medical conditions, such as wounds and cancers, but also plays an important role in improving the quality of life and health of patients. Health issues have become a great challenge worldwide. Because of the more frequent occurrence of diseases, natural disasters, traffic accidents, and population ageing, the requirement for biomedical materials in clinical applications is rapidly growing, and biomedical instruments are

predicted as a new growth point in the world economy.

There are 60 million physically challenged people out of the 1.3 billion people living in China. According to available statistical data, there are 70 million patients with osteo- porosis, more than 0.3 billion people with various dental problems, 0.15 million patients undergoing joint replace- ment surgery annually, millions of people undertaking cosmetic surgery, and more than 20 million with coronary heart disease or cardiovascular disease. Therefore, the demand for biomedical materials is very high, which is ex- pected to increase with the further development of rural markets. Unfortunately, in China, less than 5% of biomaterials and medical instruments are manufactured domestically. In addition, the availability of products required for making these biomaterials is often limited and some products may result in less satisfactory treatment outcome. Meanwhile, huge financial profits and market potential have greatly attracted overseas' companies into domestic markets, and thus the percentage of high-level products supplied by domestic enterprises are signifi- cantly reduced. Consequently, domestic enterprises are experiencing great frustration and the cost for medical treatment is subsequently increasing. To solve these prob- lems completely, independent research and development (R&D) of high-performance biomedical materials is urgently needed.

R&D of biomedical materials towards clinical translations

Translational medicine in orthopaedics has become a focus of local and international medical communities, especially in the development of biomedical materials. Biomedical materials have been developed in China for more than 20 years. However, both fundamental research and technological development are far behind that of the developed countries. In the past few years, under the support of National Natural Science Foundation of China, National Basic Research Programme of China (973 Pro- gramme), and National High Technology Research and Development Programme (863 Programme), the research of biomedical materials in China has made great progress from low-level repetition to programme-oriented and cutting- edge development in some aspects of this discipline.

For many years, the biomaterials research group of the East China University of Science and Technology (ECUST) has focused on the clinical demand-driven development and R&D of bone-tissue-repair materials. We also have tried our best to promote our research outcomes towards industrializations and clinical applications. For example, based on the biology of wound healing and the self- repairing potential of the human body, we have proposed and developed a bioreactor that possesses the function of in situ-guided tissue regeneration by synergistic ef- fects of biomaterials and growth factors. In this reactor, tissue cells can adhere, grow, and differentiate on the scaffold surface, thereby promoting new bone formation accompanied by the degradation of the scaffold materials.

Our group is the first to study calcium phosphate cement (CPC) in China. Based on the theories and method- ologies in chemical engineering, the transformation mech- anisms of specific kinds of ultrafine calcium phosphates in liquidesolid systems were thoroughly investigated. We successfully prepared CPC with high purity and high activity by a series of processes, including micromixing, heteroge- neous nucleation, heat treatment, pore formation at room temperature, and control of the degradation rate to meet biological and physiological needs in bone-defect repair. In addition, our group systematically investigated the hy- drating and hardening mechanisms of CPC. Based on these basic studies, osseointegration characteristics and degra- dation mechanisms of the prepared CPC were confirmed by in vivo animal experiments. With the superior properties of self-setting, easily shaped capability, biocompatibility, and biodegradability, we have successfully obtained the first product registration for CPC materials certified by the State Food and Drug Administration (SFDA). Our CPC has been applied in more than 500 hospitals and in over 240,000 patients in big cities such as Beijing and Shanghai. Furthermore, a series of CPC-based bone-tissue-repair materials, including drug-loaded CPC, injectable CPC, and porous CPC, has been developed (Fig. 1).

Consideration of the clinical translation of biomedical materials

The clinical translation of biomedical materials can not only effectively relieve the patients' pain and improve patients' life quality, but it can also contribute to remarkable so- cioeconomic profits. By contrast, the financial profits gained from clinical applications and the experience from clinical practice can further promote the fundamental research of biomedical materials and their R&D through virtuous cycle between basic research and clinical appli- cations. However, this is a very complicated process and requires efforts from many participating institutions, in- dustries, and regulatory bodies. Based on the experience in promoting industrialization of self-setting CPC by the ECUST, we will discuss the difficulties, experiences, and lessons in the clinical transformation process of biomedical materials .

Characteristics of the biomedical materials and their main obstacles in the process of transformation from bench to bedside.

Biomedical materials application is a relatively new branch of science with a multidisciplinary nature involving biology, materials, chemistry, and medicine. The commercialization of biomedical materials often includes laboratory research, pilot experiments, clinical trials, drug-approval programme, product registration, and marketing or clinical applications. Thus, the transformation of biomedical ma- terials to clinical applications requires a tight cooperation among government, research institutions, companies, and hospitals.
However, there are some critical issues that need to be addressed before transforming biomedical materials to clinical applications. First, research institutions, hospitals, and enterprises are independent of each other. The connection between basic research and clinical application is still poor, and thus the technology developed in a research laboratory cannot meet the demands of clinical needs. Second, chemical engineering is comparatively weak and effective engineering integration is desirable. Third, the absence of platform organizations with strong research capacity, familiar with relative law and regulatory re- quirements and market operation at the same time, results in the disconnection of research and application. Fourth, although the translation from research to clinical applica- tion is a long-term task, long-term strategic support for funds from government or enterprises with long-term development visions is often limited, which is in fact rare in developed countries. All these are critical obstacles in the effective translation from fundamental research to clinical application, and thus the rate of clinical translation of biomedical materials is very low. Low clinical translation rate and the long duration involved in obtaining product registration are the major obstacles, and these create a huge gap between research investment and the health demand in China. Therefore, great attention must be paid to find a solution to shorten the period of translation of fundamental research to clinical application, thereby accelerating the clinical translation in the field of biomedical materials.

Translational medicine platform

A good approach to bridge the gap from basic research to clinical application is to establish a translational medicine platform (TMP). The core of the TMP is to establish effec- tive ties among basic medical researchers, public health workers, and doctors, particularly to translate the biomedical research results to suitable disease prevention, diagnosis, treatment, and prevention methods effectively. Therefore, the mission or objective of TMP, from a tech- nical viewpoint, is to build a bridge between research in- stitutions and enterprises. Efficient translation and application centres or laboratories should be established, which mainly takes care of the technology development in the process of medical translation and facilitates the con- version of product R&D to clinical application [15,16]. The detailed process is summarized in Fig. 2. By contrast, from a management's viewpoint, an administration department should be established, including commission of experts, management office, and outreach coordination office, which mainly coordinate the relationships among hospitals, research institutions, and enterprises to create a novel market-oriented technological innovation, strengthen the integration process and the connection between scientific technology and management. This will facilitate the for- mation of an advanced and highly efficient management model.

TMP-based clinical translation for biomedical materials

The TMP-based clinical translation process for biomaterials will be discussed regarding the following points:
First, clinical translation of biomedical materials re- quires great attention to the relative laws and ethical issues during the whole process. The final application of the biomedical materials is for the human body, and the eval- uation of biomedical materials often includes safety, therapeutic effect, and the medical ethical issue relative laws and international practices. Therefore, the biomedical enterprises should always pay attention to the biomedical material-related constructional strategy carried out by the government and try to avoid malpractice during the process of industrialization.
Second, with regard to daily management, enterprises should closely or intensely control the quality of products and test the products carefully, ensure the safety of products and undertake the responsibility and obligation for the final quality of the products. In the meantime, the company should also establish a novel management model in line with the development of a high-tech enterprise. By these strategies, the enterprise can ignite the passions of talents and backbone and reduce the risk in the process of clinical translation.

- Optimizing supervision of the government

By studying and referring the advanced management experience of the developed countries, we should strengthen the administrative supervision, improve the level of management, and standardize the market order. Considering the specific conditions in China, we should build a unified, standardized, internationally monitored evaluation system in the field of biomedical materials. For example, various evaluation methods should be taken for different

products, and gradually improve the tightly and one-side-oriented phenomenon. The 510K contents estab- lished by the United States Food and Drug Administration is an excellent example.

First, we should change the current situation, where the registration review is strict and daily supervision is relatively loose after the product has been certified. The key problem is not certification, but close supervision in the ensuing operation and daily management. Therefore, we must combine the rigorous market certification with strict supervision. Only by combination, the contradiction between governmental effective supervision and enter- prise development can be effectively resolved. In addi- tion, the safety of the biomedical product can also be ensured.
Second, we should change the attitudes towards the domestic products. The domestic products are as important as the products fabricated for export. For the indepen- dently innovative domestic products, we should build a priority-review and fast-review programme and break out the boundary in product registration and approval. More- over, by clearing the obstacles of circulation process of biomedical materials and cleaning up the abnormal phe- nomenon during the bidding process, a better market order should be established.

Third, for promoting the development of the technology and market in the field of biomedical materials, the gov- ernment should build a domestic and international network to recruit talent, technology, resources, and management. By doing this, independent R&D centres, industry-specific common technology, and top-level talent and resources can be formed, which will subsequently result in the healthy development of biomedical materials in China.

The ideals and concepts of the founding fathers of the Indonesian nation were then translated into laws and regulations that lead to the realization of the social/economic welfare of all its citizens. 5According to Friedman, law should not only serve subjects who control the sources of prosperity and who hold economic power but must also find ways to empower individual subjects who are economically disadvantaged.6 Micro, Small, and MediumEnterprises (MSMEs) are small-scale economic activities that have various forms, so they have some definitions to describe it.

Efforts to create jobs through increasing investment, facilitating and protecting Micro, Small and Medium Enterprises (MSMEs) must be followed by policies to improve the quality of human resources 8. MSMEs in Indonesia have certain characteristics that differentiate them from large or small businesses in other countries. According to Paramita Prananingtyas, 9several characteristics that characterize small businesses include:

1. have a small business scale in terms of capital, use of labor and market orientation;
2. many are located in rural areas, small towns or suburban areas of large cities;
3. personal or family owned business status;
4. labor sources come from the socio-cultural environment (ethnic, geographical) recruited through apprenticeship patterns or through third parties;
5. work pattern is often part time or as a side business to other economic activities;
6. has limited ability to adopt technology, simple business management and administration;
7. the capital structure is very limited and the lack of working capital is very dependent on own capital sources and personal environment;
8. Business permits are often not owned and business requirements are not met.

MSMEs need to receive attention and receive special protection from the government, due to 2 (two) factors, namely: 10(1). The large number of MSME entrepreneurs in Indonesia and . There are various weaknesses or shortcomings of MSMEs when entering the free market competition system. Long history has proven that MSMEs in Indonesia have a major role, namely:

1. major player in economic activities in Indonesia;
2. provider of attractive employment opportunities, important player in local economic development and community development;
3. creation of new markets and innovation through the flexibility and sensitivity of MSMEs as well as dynamic linkages between company activities; And
4. player in improving the international balance of payments through an increasingly visible role in the composition of exports and saving foreign exchange through import substitution products linked to MSMEs.

Based on this, MSMEs should be a priority for the government's economic policy, both in the form of providing facilities and protection and in providing easy access to capital and financial matters. The empowerment of MSMEs is in line with the main goals and objectives of Long Term Development (hereinafter referred to as RPJP) for 2005- 2025, namely: 12(1) realizing an advanced, independent and just nation as a foundation for the next stage of development towards a just and prosperous society in the Republic of Indonesia based on Pancasila and the 1945 Constitution; (2) achieving the main

development targets, including: (a) the realization of an Indonesian society with noble, moral, ethical, cultured and civilized character; (b) the realization of a competitive nation to achieve a more prosperous and prosperous society; (c) the realization of a democratic Indonesia based on law and justice; (d) the realization of a sense of security and peace for all people as well as maintaining the territorial integrity of the Republic of Indonesia and state sovereignty from domestic and foreign threats; (f) the realization of a beautiful and sustainable Indonesia; (g) the realization of Indonesia as an archipelagic country that is independent, advanced, strong and based on national interests; (h) the realization of Indonesia's increasing role in international relations.

The Indonesian government prioritizes the development and empowerment of MSMEs in the National Long Term Development Plan (RPJPN) which is regulated in Law Number 17 of 2007. This plan aims to create an independent, advanced, just and prosperous Indonesia. The National Medium Term Development Plan (RPJMN) 2020- 2024 is the final stage of the National Long Term Development Plan (RPJPN) 2005-2025 so it is very important for the country's progress.

The 2020-2024 RPJMN aims to achieve development targets in Indonesia, aiming to create an independent, advanced, just and prosperous society. This is in line with the 2005-2025 RPJPN which focuses on creating a strong economic structure based on competitive advantages in various regions supported by natural resources. The MSME Law issued in 2008 regulates Micro, Small and Medium Enterprises (MSMEs) and aims to strengthen the resilience of the national economy, especially in the MSME sector. This law emphasizes empowering the business world, ensuring comprehensive, optimal and sustainable implementation of MSMEs to achieve economic growth, equality, job creation and poverty alleviation.

Mubyarto emphasized the democratic nature of the Indonesian economic system, where production is carried out by all members of society, under the leadership and ownership of community members. The prosperity and well-being of society is prioritized above individual welfare. The MSME Law aims to improve the position, role and potential of MSMEs in realizing economic growth, income, job creation and poverty alleviation.
The MSME Law in Indonesia warns against economic liberalization, especially through free market mechanisms, which could threaten the national economy, especially for MSMEs. The government's role in empowering MSMEs is outlined in Articles 7 to 15 of Chapter V concerning Business Climate Development. Empowerment is a comprehensive process involving motivators, facilitators and community groups, which aims to increase knowledge, skills and access to natural resource systems to improve community welfare. The process must include empowerment, empowerment, protection, support and reforestation.
The MSME Law mandates the government and regional governments to provide support in various aspects, including funding, facilities, business information, partnerships, licensing, business opportunities, trade promotion and institutional support. Empowerment is in line with a people's economic system which requires all levels of society to participate in planning, implementing and receiving the results of just economic activities.
The definition of empowerment in the MSME Law is efforts made by the government, regional government, business world and society in the form of climate growth and business development for MSMEs so that they can grow and develop into resilient and independent businesses. The business world includes micro, small, medium and large businesses operating in Indonesia.

Empowerment of MSMEs is carried out by adhering to several principles, namely:
1. growing independence, togetherness and entrepreneurship for Micro, Small and Medium Enterprises to work on their own initiative;
2. the realization of public policies that are transparent, accountable and fair;
3. regional potential-based and market-oriented business development in accordance with Micro, Small and Medium Enterprise competencies;
4. increasing the competitiveness of Micro, Small and Medium Enterprises; And
5. implementation of planning, implementation and control in an integrated manner.

Now, as is widely known by the public, the government has made a legal regulation containing more than one regulatory content which is considered as a reference for various kinds of legal regulations, one of which is the MSME Law which is then combined into one and hereinafter referred to as the Omnibus Law .
The Job Creation Bill changes, deletes or establishes new regulations for Micro, Small and Medium Enterprises (MSMEs), including article 6 of the MSME Law. UU no. 11 of 2020 aims to provide significant opportunities for MSMEs which currently employ 120 million of the 133 million workforce. Changes to the Job Creation Law regarding Limited Liability Companies have led to the recognition of individual legal entities that meet the MSME criteria.
The PT Perorangan model, previously known as Single Member Private Limited Liability Company

in Europe and America, Pribadian Berhard (Sdn Bhd) in Malaysia, and Private Limited Liability Company (Pte Ltd) in Singapore, has been introduced in countries such as Uganda, Ethiopia, and Pakistan. The government has introduced a new legal entity form for micro and small businesses, allowing them to establish single-level entities without the need for a commissioner or board of directors. In everyday life there are companies or business activities that are owned by individuals and carried out/run by the owners themselves.
MSEs choose individual businesses or limited liability companies (CV) to run their business, but do not choose Limited Liability Company legal entities which are characterized by capital associations and limited liability companies. The biggest obstacle for MSEs to establish a Limited Liability Company legal entity is the capital factor and business partner factors regulated in the PT Law and its implementing regulations .

A World Bank study revealed that the number of informal business entities (UMK) is greater than formal business entities such as Limited Liability Companies (PT). The World Bank believes that formal MSEs have better access to funding, better profits, and can have an impact on state taxes. To encourage the development of the MSE business, the government has made changes to the PT Law to make it easier to form a Limited Liability Company legal entity. This change is contained in Article 109 number 1 of the Job Creation Law which changes the definition of PT to "Limited Liability Company, hereinafter referred to as a Company, is a legal entity which is a capital partnership established based on an agreement. , carrying out business activities with authorized capital which is entirely divided into shares or individual legal entities that meet the criteria for Micro and Small Enterprises as regulated in the laws and regulations concerning Micro and Small Enterprises." In addition, the law allows MSEs to establish Limited Liability Companies with only one person, thereby reducing the number of informal MSEs that do not have a formal business form.

Limited Liability Companies (UMK) established by one person have been implemented in countries such as Singapore, Malaysia and the Netherlands, but have only recently been regulated in Indonesia. This raises concerns among academics and practitioners due to internal disputes and conflicts of interest. The main problem is determining the benchmark for the responsibility of limited shareholders, because the founders and shareholders are the same party. Misappropriation is prone to occur if all company shares are managed by just one person. The model of shareholder responsibility in limited companies is deemed inappropriate if applied to individual MSE companies. Minister of Law and Human Rights Regulation Number 21 of 2021 divides PT into "Capital Partnership" and "Individual", which requires company organs to represent the company in legal actions and relationships with third parties.
Individual MSE companies, which are only owned by one person, may have difficulty managing their assets due to the mix of corporate and personal assets. This is different from the PT capital association organs which include the GMS, Directors and Board of Commissioners as regulated in the PT UUPT. PP Number 8 of 2021 states that the founders, directors and shareholders of an individual company are all regulated. Directors of MSE companies, including individual companies, have the same authority as general directors in managing the company. However, shareholders in each company are not personally liable for all company agreements and are limited to the number of shares owned.

The Company Law requires a minimum of two people to establish a company, making it difficult to appoint a Commissioner or Director. This is a challenge in itself for individual MSE companies which only have one founder and shareholder. The authority of three company organs which are jointly owned by one person makes it difficult to obtain objective information for performance assessment. Although third parties can be appointed as Directors and Commissioners, this is rarely done. In addition, conflicts of interest can arise when founders, shareholders or other company organs use the company for their own interests, which can lead to violations of company law.

A single shareholder in each MSE company may hold several director positions simultaneously, which has the potential to impact the management of the company and the clarity of duties, roles, functions and responsibilities. Micro and small businesses must be managed and supervised well to avoid potential losses. Regulations must be made regarding the board of commissioners of each company. Conflicts of interest can occur in companies where the shareholder is the sole administrator due to poor financial management. Setting up a limited liability company is easier for those seeking legal entity, but is limited to micro and small businesses. Changes and dissolution can be carried out through a statement letter registered with the Minister of Law and Human Rights.

In an individual company, shareholders' personal wealth and company assets are separated, so conflicts of interest are more likely to occur. The board of commissioners is not regulated more specifically in a private company. In March 2021, the number of Micro, Small and Medium Enterprises (MSEs) in Indonesia reached 64.2 million, contributing 61.07 percent of Gross Domestic

Product. MSEs are able to absorb 97% of the workforce and collect up to 60.42 percent of total investment. The government is aware of the potential for developing MSEs, but many have not yet registered their business entities as official bodies.

In the concept of business entity, there are two categories, namely legal entity business entity and non-legal entity business entity. According to E. Utrecht, a legal entity *(rechtpersoon)* , namely a body that according to the law has the power (authority) to be a supporter of rights, it is further explained that a legal entity is any supporter of rights that does not have a soul or, more precisely, is not human. [19]Legal entity business entities are PT (Limited Liability Company), 8ustaka, and cooperatives. Meanwhile, non-legal business entities are partnerships, associations, firms, limited partnerships and limited partnerships with shares.
Legal entities have lighter legal responsibilities and are more acceptable to financial institutions. PT has legal entity status based on Law Number 40 of 2007 concerning Limited Liability Companies (UUPT). Law Number 11 of 2020 expands the definition to include capital partnerships, shares, and compliance with statutory regulations. The ASEAN free market has become a vulnerable point for MSEs and the community economy since 2015. Ease of trade, exemption from import duties and the presence of China must be taken into account. Indonesia is considering legalizing micro and small businesses (UMK) to increase efficiency and contribute to the economy. This step aims to streamline business procedures and improve the quality of MSEs. However, legal problems may arise, such as unclear legal basis, registration and announcement provisions, and the role of notaries in establishing private companies. Notaries have the authority or autohority that has been determined in statutory regulations.

Law Number 11 of 2020 and Law Number 40 of 2007 state that the establishment of a private company with one founder can result in the loss of the principle of a separate legal entity. A legal entity is a separate subject, and its assets are automatically separate from the assets of the founder. This can result in the mixing of company assets with personal assets, potentially giving rise to an abuse of the principle of limited liability .

Based on Article 10 PP No.8/2021, individual companies are required to make financial reports which are reported to the Minister of Law and Human Rights by filling in the form for submitting financial reports electronically no later than 6 (six) months after the end of the current accounting period.

To avoid misuse of company finances, the Job Creation Law requires every individual company or MSE company to make financial reports, which report their finances annually regarding the financial position report, profit and loss report, and notes to the current year's financial report.

To maintain trust in the company's management, the Job Creation Law in its implementing regulations through PP No. 8 of 2021 in Article 12 states that in the event that financial reports are not submitted by the company, the company will be subject to administrative sanctions, either a written warning, termination of access rights to services, or revocation of status. liability company. In this way, it is hoped that the principles of company management can be carried out well and avoid skepticism regarding trust in the management of MSE company businesses.

However, based on data obtained from the Directorate General of General Legal Administration, Ministry of Law and Human Rights of the Republic of Indonesia, (attached):

Shows that of the total MSEs with PT Individual legal entities, only around 0.94% of MSEs submit financial reports. It can be interpreted that the supervision carried out by the government has not been able to increase the efficiency and professionalism of implementing policies for the development and empowerment of MSEs through granting PT Individual legal entity status.

Institutional supervision is very important for the effective implementation of activities in private or public institutions. This increases efficiency and professionalism, ensuring results align with plans. Inadequate implementation can indicate three types of institutionalization: inadequate planning , inadequate human oversight, or inadequate human oversight .

Supervision is an important factor in achieving the objectives of individual company activities for MSEs, namely increasing business scale, access to capital, business competition, production of goods and services. The implementation of supervision can provide maximum benefits for improving the welfare and standard of living of micro and small business actors, and in general, supervision is carried out to achieve the goals of a welfare state .

PROVIDING LEGAL PROTECTION

According to Satjipto Rahardjo, legal protection is providing protection for human rights that are harmed by other people and this protection is given to the community so that they can enjoy all the rights provided by law. Meanwhile, according to CST Kansil, legal protection is a variety of legal measures

that must be provided by law enforcement officials to provide a sense of security, both mentally and physically from interference and various threats from any party. Philipus M. Hadjon believes that legal protection is an action to protect or provide assistance to legal subjects, using legal instruments. Lili Rasyidi and Wyasa Putra emphasized the importance of adaptive, flexible, predictive and anticipatory legal protection. Philipus M. Hadjon emphasized the need for legal protection for socially, politically and economically weak communities to create a just social order. He suggested distributing legal protection through preventive and repressive measures, ensuring community participation in decision making and judicial resolution.

Empowering Micro, Small and Medium Enterprises (MSEs) through increasing capital, market freedom and mastery of technology is very important to support the economy and encourage business competition and free markets. Legal protections, including anti-dumping laws, Trade Security Policy, and import duty regulations, are essential for fair competition.

The government provides protection for Micro, Small and Medium Enterprises (UMK) through Law no. 20 of 2008, however, this protection is often ineffective due to a lack of government supervision. Limited liability companies offer legal protection by separating personal and company assets, making it easier for MSEs to access financing. Individual companies founded by one person deviate from the principle of capital partnerships which aim at investment and profit. Accumulating shares in one person can be considered an attempt to take advantage of the legal entity's ability to raise large amounts of capital. Limited liability companies limit shareholders' liability to their own shares.

Indonesian MSMEs (Micro, Small and Medium Enterprises) face challenges due to a lack of protection and empowerment. Characteristics of underdevelopment include limited capital, poor human resources, and weak technology. Despite attention from government policies, the progress of MSEs is often inadequate compared to large businesses. Strengthening MSEs in government economic policy is often misdirected, even though the principle of legal protection is very important for the development of MSEs. In the era of economic liberalization, competition between big businesses and weak businesses is very unhealthy. Developing countries like Indonesia now view foreign investment as a useful source of working capital, managerial skills, knowledge and market connections. FDI can also increase foreign currency earnings through export activities, without incurring new debt or posing risks to the recipient country

Musa Hubeis stated that the problems, opportunities and development of MSEs in the national and global economy show what things need to be strengthened to be able to survive and what regulations need to be developed in the future, in order to achieve potential and dynamic MSEs. When connected with the principle of protection in economic law, especially regarding MSE activities.

On this basis, the forms of legal protection for MSEs in order to improve the welfare of society that must be carried out by the government are as follows:

1. Creation of a conducive policy environment for MSEs
2. Simplified terms and procedures for applying for business permits
3. Procedures for developing MSEs must be more intensive.
4. MSEs must be a priority
5. MSEs must have a partnership pattern in marketing their products
6. The implementation of coordination and control of MSE empowerment, as well as supervision of MSEs must be clear and balanced
7. Procedures for imposing administrative sanctions must be strictly regulated

PROVIDING LEGAL CERTAINTY

In law enforcement, there are three important elements that must be considered, namely: legal certainty (rechtssicherkeit) , legal usefulness (zweckmasigkeit) , and legal justice (gerechtigkeit) . If it is related to the theory of law enforcement presented by Gustav Radbruch in Idee des Recht , law enforcement must fulfill these three principles. Legal certainty is defined as clarity of norms so that they can be used as guidelines for communities subject to regulations. According to Hans Kelsen's theory of legal certainty, law is a hierarchical arrangement of norms, starting from the highest (abstract) norm and descending sequentially to the most concrete norm that can be implemented, such as a judge's decision.On the other hand, society expects benefits in implementing or enforcing the law. The existence of law not only seeks to create general justice and certainty, but also brings benefits so that the law becomes useful (doelmatig) for everyone. The essence of law is created to regulate humans, so that the implementation of law must provide benefits or usefulness for society. Usefulness is fundamental in a legal objective and its presence cannot be ignored in measuring the success of law enforcement in Indonesia. Whether a law is good or bad depends on the law's ability to provide happiness or not to humans. The community hopes for benefits in implementing and enforcing the law and avoiding obstacles and riots. If the benefits of a law have been felt by the community

then the law will be obeyed by the community without the need for coercive sanctions.

Individual Personal Trusts (PT) are mandated by the Job Creation Law and regulated in PP Number 8 of 2021 to provide legal certainty and benefits for the community, especially business actors. The government aims to encourage MSEs to survive and develop their businesses, especially during pandemic conditions. However, establishing a PT requires a statement of establishment, which is not compatible with opening a current account at a banking and financing institution. Banks still require a notarial deed, causing confusion regarding the position of the deed of establishment. To provide legal certainty, the government changed the MSE pattern from informal to formal, because most large businesses with better productivity, profits and assets are in the form of formal business entities. 41with a range of amounts 70 million to 100 million formal MSEs and 285 million to 345 million informal MSEs. 42This is where the World Bank also assesses that MSEs will be more stable in running their business if it is in a formal form, because they will get better access to funding, better profits, and have an impact on increasing state taxes. The Ministry of Law and Human Rights (KEMENKUMHAM) has introduced a new form of legal entity for MSMEs, which allows them to set up individual companies with limited liability. This new form simplifies the process of establishing a company by requiring an electronic statement form without a notarial deed. These provisions are regulated in Government Regulation (PP) Number 8 of 2021 which is a derivative of Law Number 11 of 2020 concerning Job Creation. This new form provides legal protection through separation of personal and company assets, easier access to financing, and cheaper installment taxes. The research aims to explain the benefits of legal entity form for MSMEs in terms of assets, taxes and financing. MSEs must be encouraged to establish themselves as formal business entities, because currently they provide certainty through PT. The aim is to provide various conveniences and easy access for MSEs to establish PT.

The transition from informal businesses to PT in Indonesia does not necessarily increase the number of MSEs, but reflects more professional management and attracts investors' interest in providing assistance or loans. PT as a legal entity recognizes the separation of personal assets from company assets, providing protection in the event of bankruptcy. The government also provides community protection to prevent poverty due to debt. This is possible if individuals can start an MSE as a PT without looking for a partner first.

After recognition of an individual company, the definition should also be explained clearly so that it does not give rise to a wider interpretation. Based on the characteristics and elements, an individual company can be defined as a legal entity established based on a statement of establishment from an Indonesian citizen, whose basic capital comes from the separated assets of the founder, and meets the criteria for micro and small businesses as regulated in the laws and regulations regarding business. micro and small.

Establishment

The Job Creation Law defines two types of companies and two ways of establishing them. The first is a Limited Liability Company which follows the procedures in the PT Law. Article 7 paragraph 1 states that a company must be founded by two or more people with a notarial deed. However, the Job Creation Law now regulates that a company may be founded by at least one person. The goal is for the company to be controlled by two or more people, especially in decision making. If these minimum requirements are not met then legal action and losses will be the responsibility of the founder or shareholder, this is contrary to the PT Law. A notarial deed is a very important thing because it can create legal certainty and can be used as strong evidence in the eyes of the law because of its binding and perfect nature. 44The second is an Individual Company, this type of company can be founded by one person without having to look for a business partner as long as it meets the UMK criteria. As a result, companies are founded and controlled by one person so the possibility of fraud is greater because they can take advantage of limited liability towards third parties.
The provisions of Article 153A of the Job Creation Law and Article 6 of PP 8/2021 explain that the establishment of a UMK company is established without going through a notarial deed but only by making a statement of establishment which contains the aims and objectives, business activities, authorized capital and other information relating to the establishment. limited liability company. The founding statement is then registered electronically with the Ministry of Law and Human Rights.

capital

Another implication of the Job Creation Law is the removal of regulations regarding minimum capital limits for companies. Typically, a limited liability company is required to have authorized capital, the amount of which is determined by law. 46In the provisions of Article 32 paragraph (1) of the PT Law, it is stated that the authorized capital of a company is at least IDR 50,000,000.00 (fifty million rupiah). However, this provision changed drastically in the CK Law to become as follows:

a. The Company is required to have authorized capital of the Company

b. The amount of the Company's authorized capital as referred to in paragraph (1) is determined based on the decision of the Company's founder.
c. Further provisions regarding the Company's authorized capital are regulated in Government Regulations.

Directors of the company
Company organs in Limited Liability Companies and Individual Companies are no different, according to the PT Law, Job Creation Law, and PP 8/2021. They are divided into three categories: Directors, Board of Commissioners, and GMS. Each organ has its own functions and rights to achieve company goals. The relationship between these organs is equal and each has duties and authority that cannot be contested. Directors in each company are regulated by the Job Creation Law, including financial reporting.

CONCLUSION:

The review and registration by SFDA is the most difficult and tough step for the translation of research outcome to clinical application. Different products have different evaluation requirement and standards. Therefore, to speed up the process, the TMP should establish a registration consultation company, and the researcher and enterprise should strengthen the communication with them. The registration consultation company should provide the guideline of all related policies and laws, offer assistances in file preparation, safety evaluation, and so on. The consultation company can also help the company to run registration smoothly and obtain reliable results, and thus the registration process efficiency of biomedical materials will be improved. The most important objective of this consultation company is to ensure that the research result registration is easier and efficient. In summary, China is experiencing a critical time in building a well-off society and stepping into the developed country. We should aim at the clinical demands of the country and build up TMP, where our research institutions, enterprises, and clinics shall collaborate efficiently and play their own unique role in R&D and clinical translation of biomedical materials. This collective effort will form sustainable self-innovation ability for developing biomedical materials and shorten the gap or time between R&D and industrialization. By creating innovative and novel ideas, new methods and a new strategic programme, we can make R&D of clinically orientated biomedical materials become one of the national's high- and new technology industries.

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