RJOAS: Russian Journal of Agricultural and Socio-Economic Sciences
ISSN 2226-1184 (Online) | Issue 6(150), June 2024

UDC 332

THE IMPLEMENTATION OF MINISTRY OF INDUSTRY REGULATION #16 OF 2020 ON THE SALES OF RAPID DIAGNOSTIC TEST (RDT) HEALTH EQUIPMENT

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ABSTRACT
The Indonesian government has pledged to enhance locally made goods, with one approach being the implementation of rules concerning the utilization of domestic components. The Domestic Component Level (TKDN) policy aims to increase the use of domestic products by implementing Ministry of Industry Regulation Number 16 of 2020 concerning Provisions and Procedures for Calculating the Domestic Component Level Value of Pharmaceutical Products. This research aimed to determine the implications of implementing Ministry of Industry Regulation Number 16 of 2020 concerning Provisions and Procedures for Calculating the Domestic Component Level Value (TKDN) of Pharmaceutical on the sale of Rapid Diagnostic Test (RDT) medical devices. The research method used was normative juridical by utilizing information sources from literature to understand and evaluate relevant legal provisions. The research results showed that the implementation of this regulation faces obstacles, especially related to the limited availability of domestic supplies of active raw materials, which causes high imports of active raw materials for antibodies and antigens. This results in the production price of RDT medical devices and selling prices in the domestic market being higher than imported RDTs. The legal implications indicated that a strict TKDN policy will conflict with international trade regulations related to Free Trade policies. Therefore, there is a need to improve the regulations of the Ministry of Industry to be more comprehensive and competitive in order to encourage new innovations in the use of active raw materials.

KEY WORDS
Regulations, minister of industry, TKDN pharmaceuticals, sales, RDT medical devices.

The Indonesian government policy direction outlined in the National Medium Term Development Plan (RPJMN) for the 2020-2024 periods, as stated in Presidential Regulation No. 18 of 2020, aims to enhance healthcare services for all segments of society, particularly by bolstering primary healthcare services and enhancing efforts in health promotion and prevention. This will be facilitated through the integration of innovative approaches and technological advancements. The Directorate General of Pharmaceuticals and Medical Devices is tasked with ensuring the availability and competitiveness of pharmaceuticals and medical devices. Key objectives include optimizing the provision of medications and vaccines while prioritizing product quality. Strategies involve strengthening electronic-based pharmaceutical logistics systems, intensifying promotional activities, and monitoring the judicious use of drugs. Moreover, there is a concerted effort to develop domestically produced medicines, biological products, reagents, and halal-certified vaccines, supported by research and development in life sciences, as well as the advancement of production capabilities and certification procedures for medical devices, aimed at fostering self-reliance in domestic production.

The strategic dimensions of the Directorate General of Pharmaceuticals and Medical Devices are evident when viewed through the lens of the National Health System (SKN). The SKN represents a cohesive and collaborative approach to health management involving all sectors of Indonesian society, working together towards the common goal of attaining the highest possible standards of public health (Agiwahyuanto *et al*., 2016).

Law Number 36 of 2009 concerning Health In this law, medical devices are defined as all tools, instruments, machines, implants, reagents, media, software, or other materials used individually or collectively, including software, by manufacturers or users for human medical, preventive, diagnostic, monitoring, treatment, or restorative purposes, which do not exert pharmacological, immunological, or metabolic actions, but may support such functions.

Law No. 36 of 2009 concerning Health Article 1 Paragraph 5 reads: *"Medical devices are instruments, apparatus, machines and/or implants that do not contain drugs that are used to prevent, diagnose, cure and relieve disease, treat sick people, restore health to humans, and/or form the structure and improve body function."*

Medical Devices (Alkes) include instruments, tools, machines or implants without drugs, which are used for prevention, diagnosis, treatment, disease treatment, health restoration, as well as forming structures and improving body function (Guidelines for Classification of Marketing Permits for Medical Devices, 2016).

The emergence of Ministry of Industry Regulation Number 16 of 2020 concerning Provisions and Procedures for Calculating the Domestic Component Level Value of Pharmaceutical Products began as a response to the outbreak of the Covid-19 pandemic in 2020. At that time, demand for rapid medical equipment, such as the Rapid Diagnostic Test (RDT), increased significantly. The government is trying to meet this demand by using domestically produced RDT equipment. This is what triggered the issuance of regulations related to the Domestic Component Level (TKDN).

Regarding the procurement of goods in the form of medical equipment such as Rapid Diagnostic Tests, the government has previously issued several laws and regulations, including:

- Republic of Indonesia Government Regulation Number 72 of 1998 concerning Safeguarding of Pharmaceutical Preparations and Medical Devices;
- Minister of Health Regulation Number 62 of 2017 concerning Distribution Permits for Medical Devices, In Vitro Diagnostic Health Equipment and Household Health Supplies;
- Regulation of the Minister of Health of the Republic of Indonesia Number 62 of 2017 concerning distribution permits for medical devices, in vitro diagnostic medical devices and household health supplies. Jakarta: Republic of Indonesia State News 2018 (82).

To produce medical devices of course requires a legal basis related to industry. The following are several laws and regulations related to industry:

- Law Number 3 of 2014 concerning Industry;
- Ministry of Industry, 2020, Guidelines for Increasing the Use of Domestic Products;
- Minister of Industry Regulation Number 16 of 2020 Provisions and Procedures for Calculating Domestic Component Level Values of Pharmaceutical Products;
- Food and Drug Monitoring Agency Regulation no. 19 of 2020 concerning Guidelines for Follow-Up Control of Drugs and Food.

Local Content Requirements are policies implemented by a country to ensure that some or all of the components of a product are produced domestically (Oscar and Ing, 2022). The aim is to support domestic industry, increase employment opportunities, and encourage domestic economic growth by using local resources. While these requirements provide benefits, they can also face challenges, such as rising production costs and international trade tensions. Therefore, implementation must be carefully considered to ensure a balance between benefits and impacts.

Domestic Component Level (TKDN) is a policy implemented by a country to encourage the use of domestically produced components or raw materials in making a product. The

main objective is to increase domestic economic growth, reduce dependence on imports, create jobs, and increase the added value of domestic products (Regulasi Terkait TKDN)

According to the Directorate of Domestic Product Use and Marketing, Purchasing Domestic Products (PDN) refers to the practice of purchasing goods or services produced domestically, rather than importing similar goods or services from abroad. This practice can support domestic economic growth by providing incentives to local producers to increase their production and create employment opportunities within the country. Apart from that, PDN can also help strengthen the domestic industrial sector, increase national income, and reduce the trade deficit.

Domestic Component Level (TKDN) objectives:

- Improving the domestic economy by promoting the use of local raw materials;
- Reducing dependence on imports to stabilize the economy;
- Create jobs by increasing local production;
- Increase the added value of domestic products to increase international competitiveness.

Based on regulations from the Ministry of Industry, 2020, guidelines for Increasing the Use of Domestic Products. Purchasing Domestic Products (PDN) objectives:

- Support the domestic economy by buying local products to encourage production and economic activity;
- Strengthen the local industrial sector by increasing demand and developing local technology;
- Increase national income through economic activity driven by PDN;
- Reduce the trade deficit by reducing dependence on imports.

Alternatively, as per International Trade Policies in General Agreement on Tariffs and Trade (GATT47), there are objectives that need to be achieved:

- Tariff: Tax on imported goods can be specific tariff or ad valorem. Export Subsidies: Payments to exporters to increase foreign sales;
- Import Restrictions: Direct limits on the quantity of imported goods;
- Voluntary Export Restraints: Trade restriction agreements by exporting countries;
- Local Content Requirements: Requirements regarding the minimum share or value of local goods in the product;
- Export Credit Subsidies: Loan subsidies to buyers to encourage exports;
- Government Control (National Procurement): Government purchases are directed at local products;
- Bureaucratic Barriers (Red Tape Barriers): Complicated standards and procedures as barriers to trade.

According to Law No. 7 of 1994, the Indonesian Government ratified the GATT/WTO Agreement, making it a legally enforceable commitment. This agreement embodies the idea of multilateral free trade facilitated by the World Trade Organization (WTO), of which Indonesia is a participating member.

Rapid Diagnostic Test (RDT) or rapid diagnostic test is a type of medical device used to detect the presence of disease or medical conditions quickly and easily. The components for making an RDT medical device generally consist of several important elements, although the specifications can vary depending on the type of test and the disease being targeted.

The following are the general components involved in manufacturing an RDT medical device:

- Antigen or Antibody: A substance recognized by the immune system, used as a detection agent (WHO: 2021);
- Membrane: The basis of a diagnostic test made of solid material with good capillary capacity (Alberts *et al*., 2002);
- Reagents: Used to treat samples to interact with antigens or antibodies in the sample (Reagen and Fungsinya, 2019);
- Safety Pad: The back of the membrane that provides structural support and absorbs excess sample solution (WHO: how to use RDT, 2009);

- Observation Zone: The area on the membrane where the test results can be observed;
- Absorbent: Used around the observation zone to absorb excess sample solution;
- Packaging: The components are packaged in easy-to-use strips or cassettes (Seavey, 2008).

All of these components must be carefully designed and manufactured to ensure reliable and sensitive performance in detecting targeted medical conditions. Strict quality control is also important to ensure the consistency and accuracy of rapid diagnostic test results.

Public policy theory is a conceptual framework used to understand and analyze the policy- making process and its impacts. It involves the study of how policies are created, implemented, and evaluated by governments or other institutions in an effort to solve society's problems (Awan and Yudi, 2016).

The fundamental ideas within public policy theory encompass setting the agenda, formulating policies, executing them, and evaluating their outcomes. This entails bringing topics into public discourse, planning policies, putting them into action, and gauging their efficacy. This theoretical framework aids in comprehending the intricate processes involved in crafting policies.

The notion of public policy, as outlined by Miller and Mara (2007), encompasses principles like public interest, democratic engagement, transparency, efficiency, justice, ongoing assessment, among others. These principles serve as the foundation for comprehending how governments or other entities create, implement, and evaluate policies. For instance, policies should prioritize the public interest, engage citizens actively, uphold transparency, efficiency, and social justice. Continuous evaluation is essential to gauge policy efficacy, while adaptability and collaborations are crucial to address evolving circumstances or community requirements. Altogether, these elements underpin effective and adaptable public policy.

Public policy principles serve as foundational directives, comprising moral, ethical, and strategic standards for crafting public policy. These principles aid policymakers in making well- informed choices and ensure that resultant policies align with the objectives and values of society.

Fundamental tenets of public policy encompass justice, sustainability, transparency, community engagement, coherence, efficacy, answerability, cooperation, inclusivity, and adherence to scientific standards. Policies must adhere to these standards by being equitable, considering long-term consequences, transparent to the public, engaging citizens actively, coordinated and integrated, effective and efficient (Nagel, 1986), accountable, collaborative, inclusive, and grounded in scientific evidence. These principles establish the moral, ethical, and operational underpinnings for the development of effective and enduring policies.

Good Corporate Governance (GCG) refers to a set of rules that regulate interactions between shareholders, company management, creditors, government, employees, and other parties involved, both internally and externally, in terms of their rights and obligations. Essentially, it is a framework that regulates the operations and management of a company. GCG aims to create added value for all parties involved in the company. GCG implementation (Arafat, Wilson. 2008) aims to promote transparent, professional and honest management principles, which in turn can increase investor confidence. One of the main objectives of GCG is to reduce agency conflicts and provide assurance to shareholders and investors that their interests will be safeguarded and protected. Awareness of the importance of GCG practices can also increase company transparency, and investors will appreciate the complete and clear information presented by the company, which helps them in assessing the company's performance and prospects.

Specialists emphasize the significance of Good Corporate Governance (GCG), as outlined by the National Committee for Governance Policy (2006), in addressing management issues within companies. Achieving GCG involves measures like forming an audit committee, enhancing transparency in information disclosure, appointing independent

commissioners, fostering investor relations, and linking remuneration to company performance. Wilson Arafat identified several advantages of GCG:

- Enhancing company performance by enhancing decision-making, improving operational efficiency, and delivering better services to stakeholders;
- Enhancing the company's worth;
- Boosting investor trust;
- Ensuring shareholder contentment by elevating shareholder value and dividends.

This research aimed to determine the implications of implementing Ministry of Industry Regulation Number 16 of 2020 concerning Provisions and Procedures for Calculating the Domestic Component Level Value (TKDN) of Pharmaceutical on the sale of Rapid Diagnostic Test (RDT) medical devices.

METHODS OF RESEARCH

In this research, a normative juridical method was employed, wherein the analysts scrutinized the legal norms outlined in the laws and regulations of the Republic of Indonesia concerning the Domestic Component Level (TKDN). This methodology leaned on library resources to comprehend and assess pertinent legal stipulations.

Legal research is categorized into two primary types: normative juridical and empirical juridical. Normative juridical research, as elucidated by Seomitro (1988), relies on secondary data like statutory regulations, court rulings, legal theories, and expert opinions. This approach pertains to the norms outlined in statutory regulations, serving as a benchmark for acceptable human conduct (Mukti and Yulianto, 2015). Conversely, empirical juridical research entails gathering primary data through interviews and direct observations. In the context of this legal inquiry, the researcher opted for a normative juridical approach.

This legal investigation utilizes secondary data derived from diverse sources including library resources, literature, and books, originating from primary, secondary, and tertiary legal sources. These secondary data encompass various legal materials, such as Law Number 3 of 2014 concerning Industry, Government Regulation Number 29 of 2018 concerning Industrial Empowerment, Ministerial Regulation Number PER - 08/MBU/12/2019 concerning General Guidelines for Implementing Procurement of Goods and Services by State-Owned Enterprises (BUMN), Regulation of the Minister of Industry Number 16 of 2020 concerning Provisions and Procedures for Calculating the Domestic Component Level Value of Pharmaceutical Products, and Regulation of the Minister of Industry of the Republic of Indonesia No. 31 of 2022 relating to the Domestic Component Level (TKDN) of Health Equipment and In Vitro Diagnostic Medical Devices. Additionally, secondary legal materials such as books, articles, journals, research findings, papers, and newspaper reports, as well as tertiary legal materials such as dictionaries and encyclopedias, are also employed to elucidate primary and secondary legal materials.

In this study, researchers employed both the statutory approach method and the case approach method to examine all pertinent rules and regulations. The statutory approach aids in comprehending the coherence and alignment among laws, whereas the case approach entails scrutinizing court decisions with enduring legal authority.

In legal research, data testing involved assessing the reliability, relevance, and validity of the data used. This process includes verifying data sources, analyzing methodology, detecting errors, conducting statistical tests, and confirming conclusions. Through meticulous data testing, researchers ensure the credibility of their research findings and conclusions.

In this study, qualitative analysis was utilized by researchers to comprehend theories and pertinent laws and regulations related to the research subject, aiming to provide coherent explanations concerning the legal challenges encountered. When analyzing statutory regulations, various assessment criteria were employed, such as the Pancasila Dimension, Precision of Legislative Regulation Types, Potential for Regulatory Inconsistency, Clarity of Formulation, Adherence of Norms to Content Principles, and Implementation Effectiveness.

RESULTS AND DISCUSSION

Calculation of the TKDN value of Pharmaceutical Products is carried out using weighting based on Article 4 paragraph (2). The weighting as intended in paragraph (1) consists of:

- Raw Material content with a weight of 50% (fifty percent);
- Research and Development process with a weight of 30% (thirty percent);
- Production process with a weight of 15% (fifteen percent);
- Packaging process with a weight of 5% (five percent).

Table1 – Weighting of TKDN Calculations for Pharmaceutical Products

50% Raw Material Content	30% Research and Development Process	15% Production Process	5% Packaging Process

The formulation for calculating TKDN for Pharmaceutical Products is: % TKDN = (50% x TKDN Raw Materials) + (30% x TKDN Research and Development Process) + (15% x TKDN Production Process) + (5% x TKDN Packaging Process).

Medicinal Raw Materials, hereinafter referred to as Raw Materials, are materials that are efficacious or non-efficacious which are used in the processing of Medicinal products with standards and quality as raw materials for Medicines.

Article 1 paragraph (6) Active Raw Materials are Medicinal Raw Materials that have pharmacological effects.

Article 1 paragraph (7) Additional Raw Materials are Medicinal Raw Materials that do not have pharmacological effects.

In article 5, the weight of raw material content is determined based on the following criteria: in the case of Raw Materials containing Active Raw Materials, a rating of 65% (sixty five percent) is given; And in the event that Raw Materials contain Additional Raw Materials, an assessment of 35% (thirty five percent) is given.

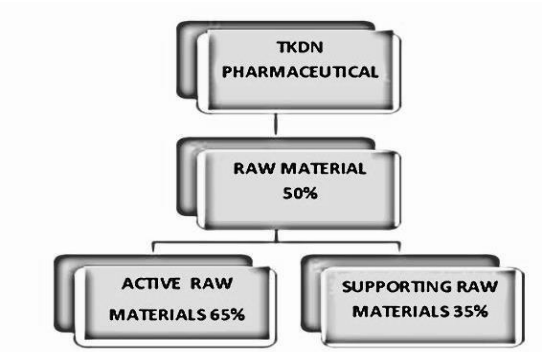

Figure 1 – Raw Material Content Weighting Parameters

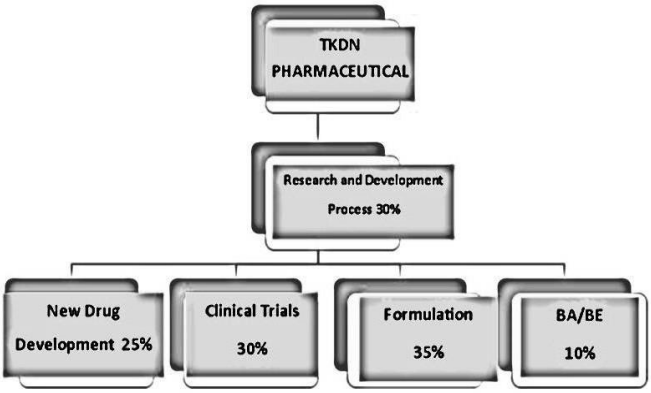

Figure 2 – Research and Development Process

Research and Development are activities carried out according to scientific principles and methods systematically to obtain data and information, which are related to understanding and proving the truth or untruth of assumptions and/or hypotheses in the health sector as well as drawing scientific conclusions for the purposes of scientific and technological progress in health.

Weighting Parameters Based on paragraph 2 Weighting of Research and Development Process article 7:

- New Drug Development is given an assessment of 25% (twenty five percent) of the total weight of Research and Development;
- Clinical Trials are given an assessment of 30% (thirty percent) of the total weight of Research and Development;
- Formulation is given an assessment of 35% (thirty five percent) of the total weight of Research and Development
- BA/BE, is given an assessment of 10% (ten percent) of the total weight of Research and Development.

Production is the activity or process of producing, preparing, processing, manufacturing, packaging and/or changing the form of Pharmaceutical Products.

Based on paragraph 3, Production process weighting, Article 17, Production process weighting is determined based on the following criteria:

- Mixing Process, given a weight of 60% (sixty percent);
- Dosage Forming, given a weight of 40% (forty percent).

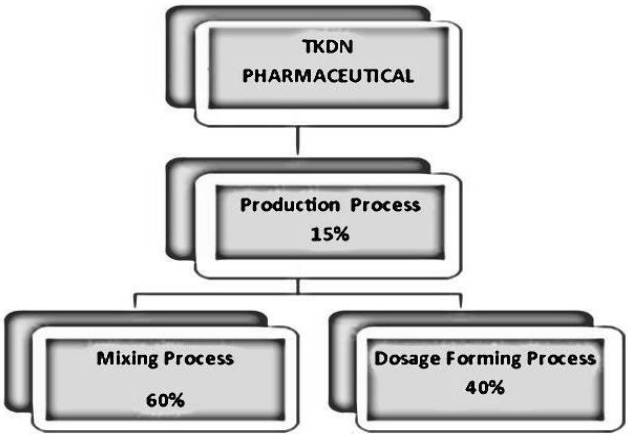

Figure 3 – Production Process Weighting Parameters

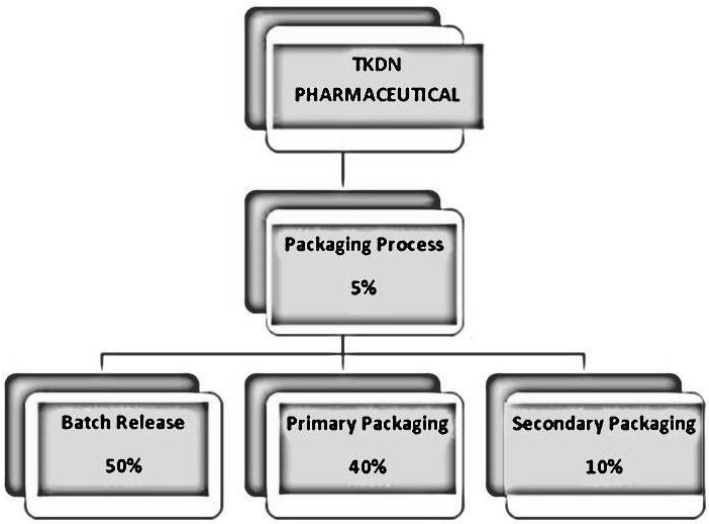

Figure 4 – Packaging Process Weighting Parameters

Primary packaging is packaging that comes into contact with the drug. Secondary packaging is complementary packaging to primary packaging.

Based on paragraph 4 Packaging Process Weighting article 20 Packaging Process Weighting is determined based on the following criteria:

- Batch Release, given a weight of 50% (fifty percent);
- Primary Packaging, given a weight of 40% (forty percent);
- Secondary Packaging, given a weight of 10% (ten percent).

PT. Asli Farma submitted TKDN verification for the 500 mg Paracetamol product in caplet dosage form. To verify TKDN Paracetamol 500 mg, the following data is provided:

- PT. Asli Farma is a company with PMDN status with 100% domestic shares;
- Active Raw Materials are obtained from abroad;
- Additional Raw Materials consist of 5 additional raw materials with details of 1 produced domestically and 4 produced abroad;
- Paracetamol is a copy drug so there is no point in developing new drugs and clinical trials;
- PT. Asli Farma carried out formulation from the start to develop and discover the drug formula for paracetamol 500 mg;
- Paracetamol is a drug that is not required for the BA/BE test, so it does not get BA/BE points.

The production and packaging process is 100% carried out by PT. Original Farma. From the data above, the following calculation results can be obtained:

Table 2 – Calculation Results of Example Questions

Weighting Factor	Description	TKDN
Raw Material Content	Active Raw Materials	-
	Additional Raw Materials	3.50%
Research And Development Process	New Drug Development	-
	Clinical Trials	-
	Formulation	10.50%
	BA/BE	-
Production Process	Mixing Process	9.00%
	Dosage Forming Process	6.00%
Packing Process	Batch Release	2.50%
	Primary Packaging	2.00%
	Secondary Packaging	0.50%

Table 3 – Recapitulation of TKDN Calculation Results for Pharmaceutical Products

Recapitulation Calculation Of TKDN Value Of Pharmaceutical Products	
Name of Goods and Services Provider Address Kind of Product	PT. Asli Farma Jl. Cempaka Putih no 444 Paracetamol 500 mg Kaplet

NO	Factors Determining Company Weight	Criteria	Final Weight Value	Maximum Weight	Sub Total Tkdn Value %
1	Raw Material Content	Available	7.00%	50%	3.50%
		No			
2	Research and Development Process	Available	35.00%	30%	10.50%
		No			
3	Production process	Available	100.00%	15%	15.00%
		No			
4	Packaging Process	Available	100.005	5%	5.00%
		No			

From the calculation above, the TKDN value is 34.00% for Paracetamol 500 mg in caplet dosage form.

After the TKDN verification has been carried out by an Independent Surveyor, from the results of this verification the Ministry of Industry can issue a valid mark or TKDN certificate for Pharmaceutical Products as in the example in the following image:

Figure 5 – Specimen of TKDN Certificate of Achievement

When Minister of Industry Regulation No. 16 of 2020 regarding Guidelines and Procedures for Determining the Domestic Component Level Value of Pharmaceutical Products was enforced amidst the COVID-19 pandemic in 2020, the demand for medical equipment surged, particularly Rapid Diagnostic Tests (RDTs), commonly referred to as Rapid Tests. Should RDT medical devices fall under Ministerial Regulation No. 16 of 2020 concerning Domestic Component Level Value for pharmaceuticals, a fresh challenge will emerge, specifically concerning Active Raw Materials.

Based on Article 6 paragraph:

- In the event that the Active Raw Materials as intended in Article 5 letter a are entirely produced domestically, an assessment allocation of 100% (one hundred percent) of the weight of 65% (sixty five percent) as intended in Article 5 letter a is given;
- In the event that the Active Raw Materials as intended in Article 5 letter a are partially produced domestically, a proportional assessment allocation of 65% (sixty five percent) as intended in Article 5 letter a is given;
- In the event that the Active Raw Materials as intended in Article 5 letter a are entirely produced abroad, an assessment allocation of 0% (zero percent) of the weight of 65% (sixty five percent) as intended in Article 5 letter a is given.

Raw materials for achieving the Domestic Content Level (TKDN) in medical devices like rapid diagnostic tests (RDTs) can differ based on the test type. Nonetheless, typical raw materials encompass plastic, paper, chemical reagents, and electronic components like sensors or chips. Active raw materials vital in RDTs typically consist of chemical reagents like antibodies, antigens, or enzymes necessary for identifying specific targets such as viruses or bacteria in samples. Furthermore, chemical substrates may also be utilized to generate color reactions indicating test outcomes.

Active raw materials in rapid diagnostic tests (RDTs) comprise antibodies and antigens, which interact to detect specific disease-causing proteins (WHO: 2021). Enzymes aid in this detection process by generating measurable signals, often through color changes. Chemical substrates facilitate these enzymatic reactions, producing signals indicating the presence of diagnostic targets. Supporting materials like plastic and paper serve as mediums for sample containment and transport. Together, these raw materials enable swift and precise target detection in RDTs.

Additional raw materials commonly utilized in rapid diagnostic tests (RDTs) include buffer solutions, which maintain ideal pH levels for chemical reactions and enhance

interactions between antigens and antibodies. Conjugates, consisting of antibodies or antigens labeled with dyes, aid in visual or optical detection. Absorbent materials ensure uniform sample flow within the test device, promoting consistent reactions and precise outcomes. Diluent solutions help dilute samples, particularly those thick or containing interfering substances. Test strips or paper serve as substrates for reactions and result display, requiring careful selection for consistent reactions and clear outcomes. These additional raw materials collectively optimize RDT performance, facilitating swift, sensitive, and specific target detection.

Some of the active and additional raw materials for rapid diagnostic tests (RDTs) can be locally produced within Indonesia. For instance, buffer solutions can be easily prepared using chemicals available locally.

But for Antibodies or antigens needed for conjugation cannot be locally produced. Advanced raw materials such as antibodies and antigens for applications in biotechnology and diagnostics are often produced in countries that have well-developed biotechnology industries. Several countries, including the United States, Europe (especially the UK, Germany, and France), Japan, and China, are prominent producers of advanced antibodies and antigens. They lead in research, development, and manufacturing due to robust infrastructure, skilled workforce, and substantial research and development support. These countries supply sophisticated raw materials for diagnostics and therapies, contributing significantly to the biotechnology industry's growth.

According to WHO, 2022, TRS 1044 - 56th report, producing antibodies for RDTs involves identifying antigens, immunizing hosts, enhancing immune responses with adjuvants, culturing cells, purifying antibodies, validating their specificity, and storing them with stabilizers. These steps ensure high-quality antibodies for reliable RDT performance.

Antigens are substances that elicit an immune response in the body, typically proteins, peptides, polysaccharides, or other molecules found on pathogen surfaces. They trigger immune responses, leading to antibody production by specialized white blood cells. Antibodies bind to antigens, marking them for destruction or neutralizing their effects. Antigens are crucial in immune defense and diagnostics, used to detect pathogens or stimulate protective antibody production. In Rapid Diagnostic Tests (RDTs), antigens serve as markers for pathogen detection or disease biomarkers in patient samples.

Overall, antibody yield, specificity, cost, and ethical considerations are important factors to consider in the production of antibodies for RDT. Balancing these factors requires careful planning, optimization, and consideration of ethical principles to ensure the production of high- quality antibodies for diagnostic applications.

The ethics of Antibody Production for Diagnostic Applications involves animal welfare (Swanson, 2008), human rights, and scientific integrity. Key principles include prioritizing animal welfare by adhering to animal welfare guidelines, applying the 3R (Reduction, Refinement, Replacement) principle, establishing humane endpoints, obtaining informed consent from human donors, protecting donor privacy and confidentiality, providing fair compensation to donors, and uphold scientific integrity. By adhering to these principles, antibody production is carried out with respect for animal welfare, human donor rights, and ethical and scientific standards.

The Ethical Principles of Antibody Production (WHO: 2022) involve regulatory compliance, intellectual property protection, transparency in contracts, responsible supply chain management, honest marketing, and ethical international trade. The integration of ethical considerations can improve reputation and build a sustainable business environment.

Legality analysis is the process of assessing and examining something, such as an action, document, or decision, to determine whether it complies with applicable law. This involves understanding the legal rules, jurisprudence, and legal principles relevant to a particular situation. The goal is to determine whether an action or decision complies with the law or whether it violates the law. This analysis is often performed by legal experts or advocates in various contexts, such as companies assessing their compliance with business regulations, or individuals checking the legality of a document before signing it.

The legality analysis for RDT production involves reviewing regulations, ensuring GMP

compliance, proper labeling, addressing patent issues, meeting marketing requirements, adhering to local and international regulations, considering environmental impacts, and understanding legal responsibilities. This ensures compliance, avoids sanctions, and maintains RDT safety and efficacy.

The active raw materials for RDT are antibodies and antigens. This material is not widely produced domestically, so this results in imports of active raw materials for antibodies and antigens.

To overcome TKDN-related challenges in RDT production, assess local raw material availability, collaborate with local suppliers, consider in-house development, seek regulatory guidance, advocate for policy changes, collaborate with industry peers, and explore alternative resource utilization. These strategies help navigate hurdles, with the approach tailored to market dynamics and company.

Business compliance is the principles and practices of ensuring that a company or organization operates in accordance with all applicable rules, regulations, standards and laws in its field. This includes compliance with government regulations, industry standards, codes of conduct, and internal company policies.

Business compliance involves adhering to legal requirements, industry standards, ethics codes, internal policies, monitoring systems, employee training, and enforcement measures. Compliance with TKDN regulations in RDT production entails meeting the required percentage of locally sourced materials.

To overcome raw material import challenges in RDT production, consider: finding alternative local sources, collaborating with research institutions, diversifying supply, negotiating with foreign suppliers, developing local production capacity, consulting regulatory authorities, innovating products, and assessing business impacts promptly. These steps ensure continued production and meet market demand effectively.

Legal consequences for violators of RDT production may vary depending on the country, regulations, and seriousness of the violation. However, Businesses violating RDT production rules face consequences like administrative sanctions, lawsuits, production cessation, criminal prosecution, product removal, reputation damage, and regulatory scrutiny. Compliance is crucial for public health and maintaining business continuity and reputation.

TKDN (Domestic Content Level) in the pharmaceutical sector, including RDT production, faces weaknesses such as dependence on imported raw materials, higher production costs, inconsistent quality and quantity, limited local production capacity, risk of supply interruption, and slow industry growth. However, TKDN also supports local industry development, enhances production independence, and creates jobs. With proper management and strategy, these weaknesses can be mitigated for TKDN to benefit the economy and society.

The weaknesses related to Minister of Industry Regulation no. 16 of 2020 on Pharmaceutical TKDN for RDT medical devices include regulatory complexity, administrative costs, local supply limitations, risk of supply cutoff, lack of flexibility, difficulty in achieving TKDN value, delays in implementation, and increased production costs. These challenges can hinder compliance and increase operational burdens for pharmaceutical companies.

To address these challenges, improving communication between the government and the pharmaceutical industry is crucial, along with ongoing evaluation of regulation implementation. Minister of Industry Regulation no. 16 of 2020 on TKDN values for pharmaceutical products faces obstacles due to the ongoing Covid-19 pandemic, leading to a shortage of domestically produced medical devices like RDTs. This shortage results from heavy reliance on imported active raw materials, which make up 90% of the supply. Consequently, the prices of locally produced RDTs with TKDN compliance have increased, making them more expensive compared to imported alternatives.

The analysis in this section will provide an in-depth understanding of how these regulations impact the RDT medical device industry ecosystem as a whole.

The findings provide a concrete picture of how regulations can affect various aspects of the RDT medical device industry.

Table 4 – Table of Regulatory Impact on the RDT Medical Device Industry

Regulatory Impact Aspects	Impact Description	Findings
Production Standards	The influence of regulations on production standards and RDT product quality.	Regulations may require companies to update their technology or production processes to meet more stringent standards.
Industrial Competition	The impact of regulations on competitive dynamics between companies in the RDT industry.	Stricter regulations may reduce the number of competitors in the market, giving a competitive advantage to companies that can better comply with regulations.
Product Innovation and Development	How regulations affect a company's ability to innovate and develop new products.	Stricter regulations may reduce investment in research and development as companies must focus on compliance with existing regulations.
Compliance Costs	Financial impact of regulatory compliance.	Compliance costs such as product testing or infrastructure updates may increase production costs significantly.
Market and Distribution	The influence of regulations on market access and distribution of RDT products.	New regulations may require companies to update or expand their distribution networks to comply with new requirements.
Business Ethics and Social Responsibility	How regulations affect corporate social responsibility and business ethics.	Stricter regulations may encourage companies to increase transparency and accountability in their business practices.
Revenue and Profit	Direct impact on company revenue and profits.	Regulations that limit sales or introduce additional taxes may reduce a company's revenues and profits.

The following is a table showing the impact of the Minister of Industry's TKDN policy on social, economic and environmental aspects along with examples and detailed explanations:

Table 5 – Table of the impact of TKDN policy on socio-economic and environmental aspects

Aspect	Impact	Example & Details
Social	Creating new jobs	Example: The construction of a new factory provides jobs for local people who were previously unemployed. Explanation: TKDN policy can trigger the growth of domestic industry which requires additional labor. This can reduce unemployment rates and improve social welfare. However, companies need to ensure that working conditions are decent and fair.
Economy	Increasing the competitiveness of domestic industry	Example: Encouraging the use of local components in electronics production increases market share for domestic products. Explanation: By implementing the TKDN policy, the government can encourage domestic industry to be more competitive with imported products. This can increase the country's foreign exchange earnings and increase overall economic growth. However, this can also present challenges for industries that are not yet ready to compete.
Environment	Encourage sustainable use of natural resources	Example: Adopting more environmentally friendly production technology to reduce waste and carbon emissions. Explanation: TKDN policy can encourage industry to reduce dependence on non-renewable natural resources and adopt more environmentally friendly production practices. This can reduce negative impacts on the environment such as air and water pollution and deforestation. However, companies need to invest in appropriate technology and infrastructure.

The TKDN policy may lead to unexpected impacts:

- Lower Product Quality: Inability to match imported standards might reduce the quality of domestically produced goods;
- Higher Production Costs: Reliance on costlier domestic resources or technology could raise production costs and consumer prices;
- Trade Disputes: Protectionist TKDN policies may violate international trade rules, leading to disputes and economic repercussions;
- Economic Power Concentration: Favoring larger companies may consolidate market dominance, hindering smaller businesses;
- Innovation Stagnation: Restricted access to global technology might impede innovation and slow technological progress.

The following is a comparison table between the positive and negative implications of TKDN from an economic perspective:

With this table, we can see how TKDN can have various impacts on economic aspects, producing positive benefits as well as negative challenges and risks.

Table 6 – Comparison Table between positive implications and Negative TKDN from an economic perspective

Positive Implications of TKDN from an Economic Point of View	Negative Implications of TKDN from an Economic Point of View
Increased local economic growth	Additional production costs
Economic diversification	Decrease in the competitiveness of local products
Increased investment in infrastructure	Product launch delays
Increased global competitiveness	Stunted economic growth
Creation of new jobs	Potential reduction in product variety

The following is a table showing the view of business law regarding the negative impacts of the TKDN policy along with examples and explanations:

Table 7 – View Business Law regarding the negative impact of the TKDN policy

Aspect	Business Law View	Examples and Explanations
International Legal Compliance	It is important to ensure that TKDN policies comply with applicable international trade rules.	Example: If the TKDN policy violates WTO rules, companies operating in that country may face trade sanctions from their trading partner countries.
Protection of Intellectual Property Rights	It is necessary to pay attention to the protection of IPR when designing TKDN policies.	Example: If the TKDN policy requires the use of technology without regard to patent rights, the company may be involved in a legal dispute over violation of intellectual property rights.
Impact on Market Competition	It must be evaluated to ensure it does not hinder fair competition in the market.	Example: If the TKDN policy provides preferential treatment to local companies, this could create barriers to entry for imported products and harm competition
Corporate Social Responsibility (CSR) Obligations	Companies must consider the impact of TKDN on corporate social responsibility.	Example: If TKDN policies result in a deterioration of working conditions or environmental damage, companies may be violating their CSR principles and risk damaging their reputation.
Impact on Innovation and Technological Progress	It is important to consider the effect of TKDN policies on companies' incentives to innovate.	Example: If the TKDN policy hinders companies' access to the latest technology, this could slow down the pace of innovation and technological progress in the country.

From a business law perspective, careful evaluation of the negative impact of TKDN policies in these aspects is necessary to ensure compliance with applicable laws and to avoid legal risks that have the potential to harm the company. In the context of legal economic analysis, careful evaluation is needed to ensure that the application of TKDN in the pharmaceutical industry does not result in detrimental consequences for society and the economy as a whole.

Table 8 – Table of the Negative Impact of Implementing TKDN in the Pharmaceutical Industry on RDT Sales

Impact	Explanation	Real Example / Findings
Supply Limitations	TKDN regulations requiring high levels of domestic components for RDTs may result in supply constraints as local producers may not be able to meet demand quickly or in sufficient quantities.	During the COVID-19 pandemic, demand for RDTs increased dramatically, but several countries experienced supply constraints as local manufacturers were unable to meet the rapidly increasing demand.
Additional cost	The process of meeting TKDN standards may require additional investments in infrastructure, technology, or human resources, which can increase overall production costs. These additional costs can then be passed on to consumers in the form of increased RDT prices.	A local pharmaceutical company had to build a new production facility and train employees at significant additional costs to meet TKDN requirements, which then resulted in an increase in RDT prices.
Decreasing Competition	TKDN rules that provide unfair competitive advantages to local producers can result in decreased competition in the market. This lack of competition can result in lower product quality and higher prices for consumers.	In certain countries, TKDN regulations provide large subsidies to local RDT producers, which inhibit the entry of foreign producers and results in increased prices and reduced innovation in RDT products.
Insufficient Local Technology Dependence	Restricting access to imported technology without adequate promotion of local technological development may result in reliance on less sophisticated or less efficient technology, affecting the quality and effectiveness of RDTs.	A country implements TKDN regulations that prohibit imports of the latest technology for RDT production, but the available local technology is not advanced enough, causing the quality of RDTs to be
Inhibition of Innovation	Excessive focus on meeting TKDN requirements may hinder technological progress and the development of more effective RDTs, limiting progress in disease detection and better treatment.	A local pharmaceutical company preferred to allocate resources to meet TKDN requirements rather than undertake new research and development to improve the effectiveness of existing RDTs.

Based on factual data from sales of Rapid Diagnostic Test (RDT) medical devices from 2020 to 2023, the following figure shows:

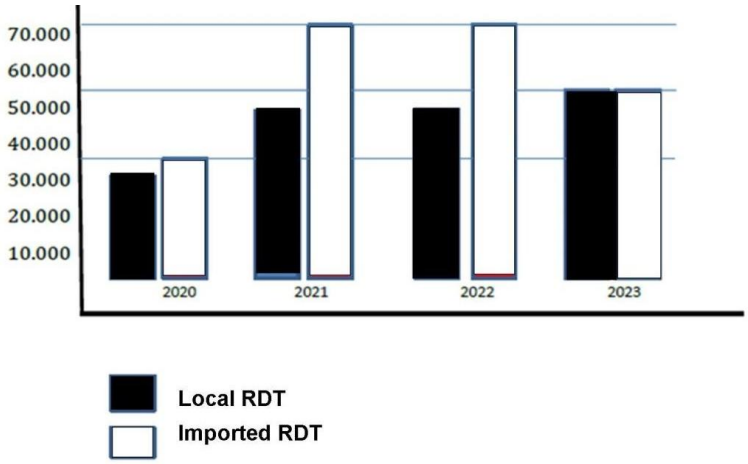

Figure 1 – RDT Medical Device Sales 2020-2023 (Source: Field survey from sales data of RDT medical equipment distributors in Jakarta, in 2023)

At the beginning of the pandemic, demand for RDT medical equipment at the end of the year was recorded locally at 30,000 batches, which was lower than demand for imported RDTs at 35,000 batches. However, in 2021 and 2022 demand for local RDTs and imported RDTs will increase 2 times more than in 2020. In 2021 and 2022 local RDTs will be 45,000 batches while imported RDTs will be 70,000 batches. Notes: 1 batch = 25 units.

Table 9 – Comparison table between imported rapid tests and local rapid tests

Aspect	Imported Rapid Test	Local Rapid Test
Production cost	Tends to be lower due to currency advantages or low production costs in the country of origin	Tends to be higher due to higher labor, raw material, or infrastructure costs
Quality	Quality can vary, but is often considered good because it is produced by an established company	Quality may vary, but can be good if manufactured by a trusted company and adheres to strict quality standards
Availability	Easy to find and widely distributed due to an established distribution network	May be more limited in availability and distribution, especially if production has not yet reached large scale
TKDN Commitment	May have a low TKDN contribution because it is produced abroad	More likely to meet TKDN requirements and have higher levels of domestic components
After Sales Support	Technical support and after-sales service may be limited and slow due to long geographic distances	It may offer better technical support and after-sales service because it is geographically closer to consumers

The increase in demand for imported RDT products during the Covid-19 pandemic was attributed to factors such as perceived better quality, lower prices, and greater availability compared to local RDTs. A field survey involving consumers and producers revealed these reasons:

- Quality: Imported RDTs are deemed of better quality for practical use and are readily available on the market, unlike local RDTs, which may face production delays;
- Price: Imported RDTs are cheaper as they come with all necessary raw materials, while local RDTs face higher costs due to constraints in sourcing active raw materials;
- Supply: There is a higher supply of imported RDTs in the market due to production delays in local raw materials for antibodies and antigens.

The comparison between imported and local rapid tests highlights several factors:

- Cost: Imported tests may have lower production costs, while local tests may incur higher costs due to labor, raw materials, and infrastructure;

- Quality: Imported tests may be perceived as higher quality due to testing and manufacturing standards, but local tests can also meet quality standards if produced by trusted companies;
- Availability: Imported tests may be more widely available and distributed due to established networks, while local tests may have limited availability;
- TKDN Compliance: Local tests are more likely to comply with TKDN requirements, while imported tests may have lower TKDN contributions;
- Support: Local tests may offer better technical support and after-sales service due to proximity, while imported tests may have limited support.

When choosing between imported and local rapid tests, factors such as cost, quality, availability, TKDN compliance, and support should be considered based on specific needs and preferences.

This table provides a comparative overview between imported and local rapid tests based on field findings regarding several important aspects in product selection.

CONCLUSION

The enforcement of Minister of Industry Regulation No. 16/2020 on Pharmaceutical TKDN influences various aspects including production standards, industry competition, innovation, compliance expenses, market dynamics, business ethics, and revenue. Additionally, it affects government adherence and assistance, supply chain operations, competitiveness, production expenditures, retail prices, and product advancement. Furthermore, it carries implications for legal repercussions such as penalties and claims, reputation, and adherence to contracts with ongoing oversight.

Viewed through an economic lens, the enforcement of Minister of Industry Regulation No. 16/2020 regarding Pharmaceutical TKDN may result in heightened production expenses, diminished competitiveness of domestic goods, and postponement of product introductions. Socially, this could potentially limit accessibility to affordable products, pose challenges in meeting consumer demands, and exacerbate economic disparities and societal tensions. Environmentally, the implementation of these regulations may escalate natural resource consumption, waste generation, environmental pollution, and harm to habitats and biodiversity.

From a standpoint of business law, the enactment of Minister of Industry Regulation No. 16/2020 concerning Pharmaceutical TKDN influences aspects such as adherence to international legal standards and protection of intellectual property rights, market competitiveness and corporate social responsibility, as well as advancements in innovation and technology. From a legal-economic perspective, the enforcement of these regulations impacts factors like economic efficiency and competition, pricing and innovation, and accessibility and equity.

The adoption of TKDN within the pharmaceutical sector adversely affected sales of RDTs, resulting in constraints on supply, diminished competition, and a slowdown in innovation. The preference for imported RDT medical devices is driven by their lower production costs, high quality from reputable manufacturers, and widespread availability and distribution. Hence, the selection of imported RDTs is motivated by their superior quality, lower prices due to the inclusion of Antibody and Antigen raw materials, and broader market accessibility.

Given the constraints of the present study in terms of time and scope, further extensive research is warranted in the future to gain a deeper understanding of the effects of enacting and enforcing Legislative Regulations. This includes examining its ramifications on social, economic, and environmental dimensions to provide a more comprehensive insight.

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