

Government's Policies at A Glance : The Promotion of Domestic Pharmaceutical and Medical Devices Industries



Directorate General of Chemical, Textile, and Multivarious Industry

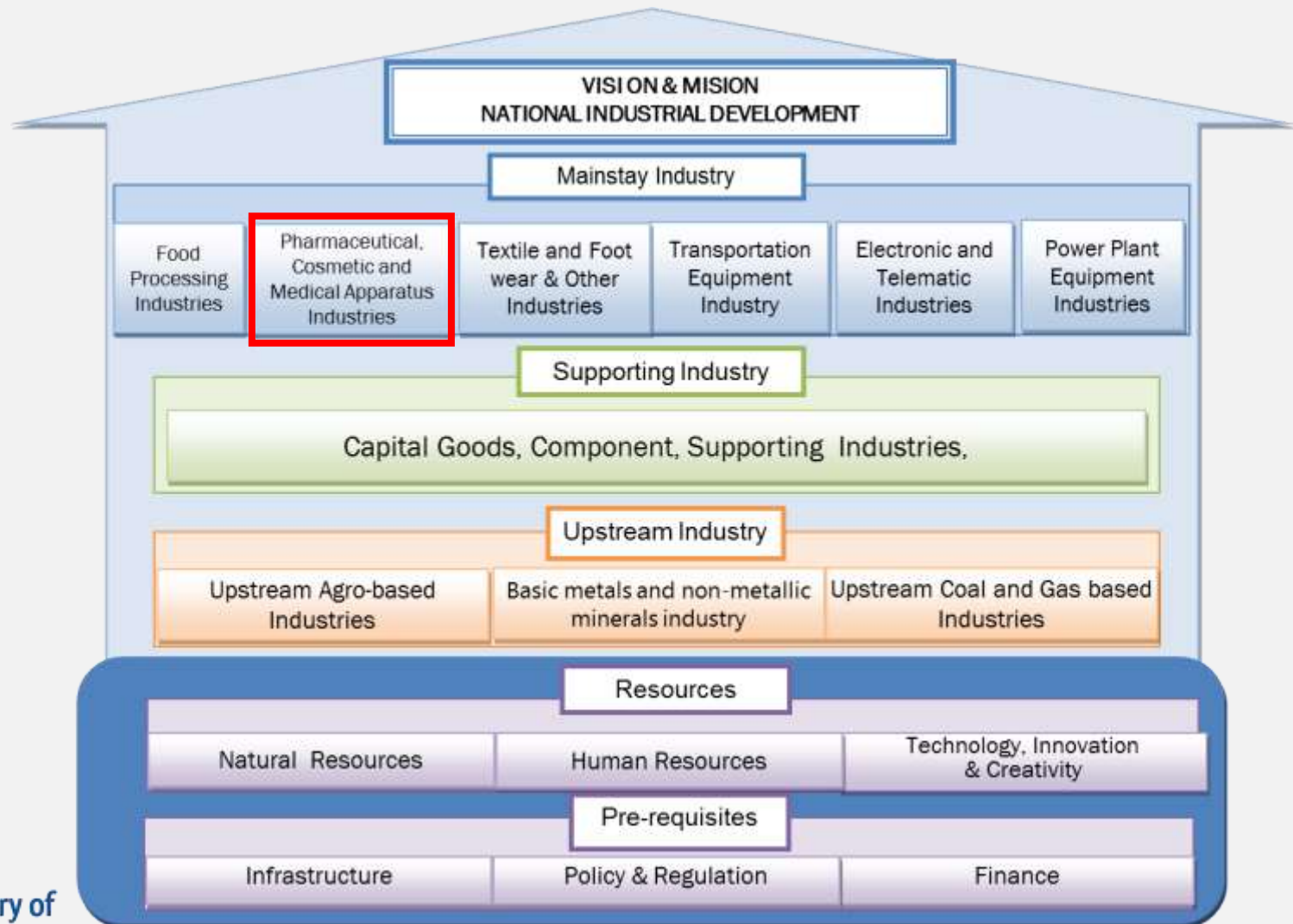
On

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PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRIES IN INDONESIA

STRUCTURE OF NATIONAL INDUSTRY



PHARMACEUTICAL AND MEDICAL DEVICES: DEVELOPMENT OBJECTIVES

Ensuring the Availability of Drug and Medical Devices to support Government program on National Health/JKN

Health Spending in 2015 reached Rp 414 Trillion, 15% (Rp 62,4 Trillion) are for Medicine

Enhancing Competitiveness of Pharmaceutical and Medical Devices Industries

- Export of Pharmaceutical products (2014) USD 532 million
- Export of Medical Equipment (2014) USD 165 million.

Mastery of Knowledge and Technology in Pharmaceutical and Medical Devices Industry

- Formulation and Development of Pharmaceutical Ingredients and biotechnology
- *middle-low* technology for Medical Devices Industries with low and medium risk.

Improving Resilient in availability of Drug and Medical Devices

- Pharmaceutical supplies are 76% from domestic and 24% from import
- 95% of pharmaceutical ingredients and 94% of medical devices are imported

PERFORMANCE OF INDONESIA'S PHARMACEUTICAL AND MEDICAL DEVICES 2015

PHARMACEUTICAL INDUSTRY

DESCRIPTION	State	Private	MNC	Total
Industry	4	178	24	206
Sales (Rp Trillion)	45,69		16,46	62,14
Percentage (%)	74%		26%	100%
Avg Sales Growth 2011 – 2015 (%)	11.9%		11.0%	11.7%

MEDICAL EQUIPMENT INDUSTRY

DESCRIPTION	State	Private	MNC	Total
Industry	2	164	29	195
Sales (Rp Trillion)				12
Avg Sales Growth 2010 – 2014 (%)				12.8%

Health Spending in Indonesia cost 2,7% of GDP, lower than Malaysia (3,8%), Thailand (4,1%) and Singapore (4,9%).

Characteristics of Pharmaceutical Industry



Capital Intensive



High Technology



Knowledge (R&D)
Intensive



Heavily Regulated

ROADMAP OF DEVELOPMENT OF PHARMACEUTICAL INDUSTRY (2015 – 2025)

API	2015-2018	2019-2022	2023-2025
BIOPHARMACEUTICALS	EPO; GCSF; Probiotic; Insulin; Stem cell protein; Somatropin; EGF; Enoxaparin	Blood Fractionation; Growth Hormone; Interferon; Trastuzumab; Insulin; MAB	MAB; Insulin analogue
VACCINE	Dengue; MR; HB; Hexavalent; Sabin IPV; Rotavirus; Typhoid Vi-Conj; Rabies	DTaP; Hexavalent; MenACWY; New OPV type 2; Pneumococcal; Rotavirus; Rabies	HPV; New TB Recombinant
NATURAL	Dehidro-di-Isoeugenol; Curcumin; Gingerol; Phylantin; Piperin; Steviosid; Xanthorhizol; Zederone; Ekstrak sambung nyawa; Ekstrak temulawak; Ekstrak seledri; Ekstrak kumis kucing; Palm sugar; Ekstrak Cinnamomum burmanii; Fitoestrogen; Dermifix Wound Healing	Glucosamin; Omega-3; Resveratrol; Vinca alkaloid derivatives; Isolat gandarusa; Isolat alga coklat; Isolat mikroba simbion karang laut; Isolat Guazuma longifolia	Andrographolide; Etil-p-metoksi Sinamat; Ekstrak cacing tanah
CHEMICALS	Statin derivatives; Pantoprazole; Clopidogre; ARV; Beta-Lactam (amoxillin); Pharma Salt; Dextrose pharma-grade; Lyophilisation substances; Magnesium stearate; Paracetamol	Ascorbic Acid; Cephalosporin; 7-AVCA; 7-ACCA; 7-ADCA; ARV	

10 BESAR RENCANA KEBUTUHAN OBAT NASIONAL TAHUN 2015



- From 939 variety of Drugs in “Rencana Kebutuhan Obat Nasional 2015”, still dominated by basic medicine : vitamin B; pain killer (analgesik), antipiretik (Paracetamol); and antibiotics (Amoxycillin).
- In 2015, sales of pharmaceutical products reached Rp 62,1 Trillion (Source: IIMS survey Q4-2015)

Type of Industry in The Development of Pharmaceutical and Cosmetic Industry

(Masterplan of Development of National Industry 2015 – 2035)

Type of Industry		
2015-2019	2020-2024	2025-2035
<ol style="list-style-type: none"> 1. Herbal Preparation 2. Salt Pharmaceutical Grade 3. Cephalosporins 4. Amlodipine 5. Glucose pharmaceutical grade (for infusion) 6. Amoxicillin 7. Glimepiride/ Metformine 8. Paracetamol 9. Biologic Product 10. Vaccine 11. Herbal/Natural Product 12. Excipient 	<ol style="list-style-type: none"> 1. Lanzoprazole 2. Vitamin C 3. Atorvastatine 4. Beta-caroten 5. Stevioside 6. Simvastatine 7. Biologic Product 8. Vaccine 9. Herbal/Natural Product 10. Excipient 	<p>Capacity Development (Export Oriented):</p> <ol style="list-style-type: none"> 1. Herbal Preparation 2. Salt Pharmaceutical and Industrial Grade 3. Cephalosporins (mixed) 4. Amlodipine 5. Glucose pharmaceutical grade (for infusion) 6. Amoxicillin 7. Glimepiride/ Metformine 8. Paracetamol 9. Lanzoprazole 10. Vitamin C 11. Atorvastatine 12. Beta-caroten 13. Stevioside 14. Biologic Product 15. Vaccine 16. Herbal/Natural Product 17. Osmanthus Talc 18. Excipient

Programme 2015 - 2035

2015-2019	2020-2035
<ol style="list-style-type: none">1. Improving process technology and engineering of pharmaceutical and cosmetic product through integrated R&D2. Facilitating the development of raw material for pharmaceutical and cosmetic industry in order to substitute imported raw3. Enhancing the usage of domestic product and improving the linkage between large industries to SMEs4. Strengthening infrastructures in order to support the implementation of Indonesian Standard of Pharmacopoeia in pharmaceutical and cosmetic industry5. Developing petrochemical industry to reduce imported raw material6. Developing research and manufacturing of standardized and integrated biotechnology and herbal product7. Developing competencies and capabilities in the research of biotechnology and herbal product8. Improving technology and developing the capabilities in manufacturing process according to international standard9. Improving the capabilities in clinical test	<ol style="list-style-type: none">1. Developing technology to produce raw materials of pharmaceutical and cosmetic2. Facilitating the development of pharmaceutical and cosmetic industry in large scale and export oriented3. Facilitating accredited test laboratory4. Improving the transfer of technology of each pharmaceutical products and raw materials

ROADMAP OF MEDICAL DEVICES INDUSTRY DEVELOPMENT OBJECTIVES 2015 - 2025

2015 – 2019	2020 - 2024	2025 - 2035
1. Disposable & Consumables Products	1. Disposable & Cosumables Products	1. Disposable & Cosumables Products
2. Hospital Furniture	2. Hospital Furniture	2. Hospital Furniture
3. Implan Ortopedi	3. Implan Ortopedi	3. Implan Ortopedi
4. Electromedical Devices	4. Electromedical Devices	4. Electromedical Devices
5. Diagnostic Instrument	5. Diagnostic Instrument	5. Diagnostic Instrument
6. PACS (Picture Archiving & Communication system)	6. PACS (Picture Archiving & Communication system)	6. PACS (Picture Archiving & Communication system)
7. Software & IT	7. Software & IT	7. Software & IT
8. Diagnostics Reagents	8. Diagnostics Reagents	8. Diagnostics Reagents
	9. POCT (Point of Care Testing)	9. POCT (Point of Care Testing)
	10. Radiologi	10. Radiologi

From 378 variety of medical equipment , Total Demand in 2015 are 50.213 unit or cost Rp 9,75 Trillion (Kemenkes)

Programme 2015 - 2035

2015-2019	2020-2035
<ol style="list-style-type: none">1. Developing policy in order to engage mass medical devices industry with health financing in a “cross-subsidy” form2. Developing policy concerning the usage of domestic medical devices in health facilities and services that are funded by State Budget3. Facilitating the promotion of the usage of domestic medical devices, including training and spare-part/maintenance guarantee4. Developing road-map of medical device industry, integrated with related technology, including component, raw material, and intermediate material5. Building center of excellence including R&D and production of mass basic medical devices for domestic purpose6. Developing human resources with high competency in engineering-design of medical devices, including testing and calibrating7. Facilitating the financing of capacity expanding of mass basic medical devices industry through revitalization of machinery and calibrating device8. Developing standardization and supporting of Intellectual Property Right of domestic medical devices9. Developing and strengthening the modern SMEs of components of medical devices through technical support and testing devices	<ol style="list-style-type: none">1. Developing and strengthening the capability, quality, and efficiency of medical devices industry2. Developing technology and human resources in application-design of medical devices and bionic (artificial organs) which is integrating aspects of health, biology, material, cognitive, and micro/nano-electronics3. Building center of excellence including R&D and production of mass basic medical devices for domestic purpose4. Developing standardization and supporting of Intellectual Property Right of domestic medical devices5. Developing and strengthening the modern SMEs of components of medical devices

List of Medical Devices Industries in Indonesia



PT. Andini Sarana

PT. Arista

PT. Chitose

PT. Dharma Medipro

PT. Dharma Polimetal

PT. Gresik Sarana Tirta/PT. St Regensia Indonesis

PT. Lestari Dini Tunggul

PT. Mega Andalan Kalasan

PT. Nuri Teknik

PT. One Med

PT. Saptindo Surgica

PT. Sarandi Karya Nugraha

PT. Segara Husada Mandiri

PT. Shima Prima Utama

PT. Sugih Instrumendo Abadi / ABN

PT. Tecnomed Asia

PT. Tesena Inovindo

PT. Trimitra Gamedindo Interbuana

Center for Development of Medical Devices Technology and Industry (PPTI-Alkes)

- Cooperation between Ministry of Industry and Bandung Institute of Technology (ITB)
- Building construction started in 2013 at ITB Area and still in process of fulfilling the R&D devices
- Tasks:
 - ✓ Developing technology of medical devices
 - ✓ Enhancing the development of medical device industry
- Main activities:
 - ✓ R&D of technology of medical devices
 - ✓ Human resources development/training
 - ✓ Technical services

Center for Development of Medical Devices Technology and Industry (PPTI-Alkes)

R & D

STUDY

- MODELLING A-B-G CORRELATION
- STUDY OF GOVERNMENT'S POLICIES
- MAPPING THE CAPABILITIES OF MACHINE TOOLS INDUSTRIES
- MAPPING THE NEEDS OF MACHINE TOOLS INDUSTRIES
- DEVELOPING CURRICULUM OF HEALTH TECHNOLOGY

RESEARCH

- CONSTRUCTION THE COMPONENTS OF MEDICAL DEVICES
- TECHNOLOGY OF RAW MATERIALS OF MEDICAL DEVICES
- SUPPORTING TECHNOLOGY OF MEDICAL DEVICES
- MANUFACTURING TECHNOLOGY OF MEDICAL DEVICES
- REGULATION/STANDARD OF MEDICAL DEVICES
- STANDARDIZATION AND CALIBRATION TECHNICS OF MEDICAL DEVICES

HUMAN RESOURCES DEVELOPMENT

TRAINING

- CALIBRATION AND TESTING OF MEDICAL DEVICES
- USAGE AND MAINTENANCE OF MEDICAL DEVICES
- SPECIFIC TRAINING
- CERTIFICATION OF PERSONNEL

CASE STUDY

- STUDENTS IN BACHELOR, MASTER, AND DOCTORAL PROGRAM

INDUSTRIAL SERVICES

TECHNICAL CONSULTATION

- DESIGN AND ENGINEERING OF MEDICAL DEVICES
- PRODUCTION PROCESS PLANNING
- PRODUCTION PROCESS OPTIMIZATION
- QUALITY CONTROL AND DEVELOPMENT OF PRODUCT
- REGULATION/STANDARD OF MEDICAL DEVICES

TECHNICAL SUPPORT

- MAINTENANCE AND REPAIR OF MEDICAL DEVICES
- DESIGN AND ENGINEERING OF MEDICAL DEVICES
- DESIGN AND ENGINEERING OF PRODUCTION PROCESS OF MEDICAL DEVICES
- CERTIFICATION AND CALIBRATION OF MEDICAL DEVICES
- PACKAGING & LABELING

LOCAL CONTENT (TKDN) POLICY

Presidential Instruction No. 6/2016 : Acceleration on the Development of Pharmaceutical and Medical-Devices Industry

Ministry of Industry is addressed to:

- Establish policies in order to support the development of pharmaceutical and medical-devices industry
- Monitor and evaluate the implementation of Local Content (TKDN) policy in the field of pharmaceutical and medical-devices
- Increase the supply of chemical raw-material and components in pharmaceutical and medical-devices industry

REGULATION

**Presidential Instruction No. 02/2009 :
The Usage of Domestic Product in Government's Procurement of
Goods/Services**



**Presidential Regulation No. 70/2012 :
Amandment to Presidential Regulation No. 54/2010 regarding
Government's Procurement of Goods/Services**



**Regulation of Minister of Industry No.
49/2009: Guidance of The Usage of Domestic
Product in Government's Procurement of
Goods/Services**



**Regulation of Minister of Industry No.
02/2014: Guidance of The Usage of Domestic
Product in Government's Procurement of
Goods/Services**



**Regulation of Minister of Industry No.
102/2009: Amandment to Regulation of
Minister of Industry No. 49/2009**



**Regulation of Minister of Industry No.
16/2011: Provision and Procedures for
Calculation of Local Content (TKDN) and
Company Benefit Value (BMP)**

DEFINITION

UU No. 3 / 2014

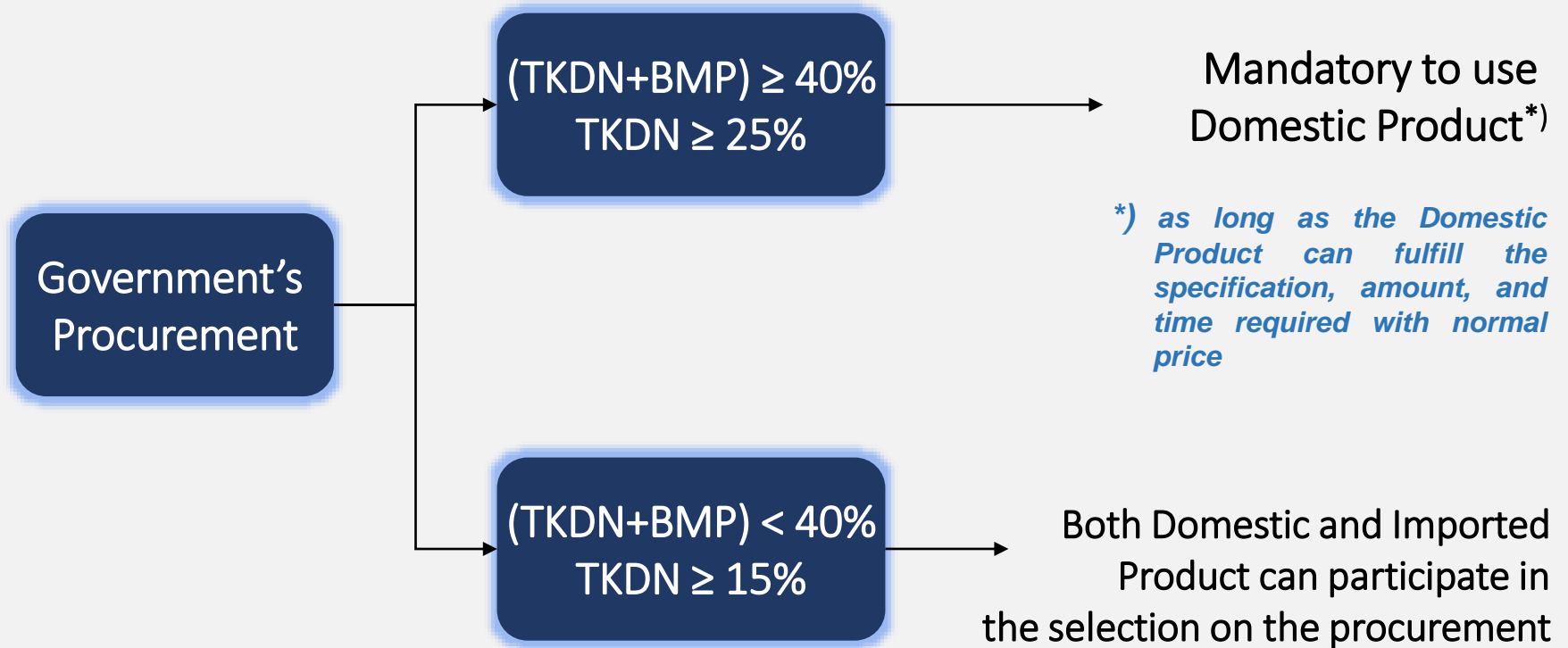
Industry is the whole economic activity that process material inputs and / or using industrial resources to produce goods and services which has added values and benefit.

Local Content is a series of act that process material inputs in domestic, by using variety of input component from domestic or imports, to create goods or services which has added value

Local Content (TKDN)

$$\%TKDN = \frac{\text{Domestic Component}}{\text{Domestic Component} + \text{Imported Component}} \times 100\%$$

- **The component** consists of :
 - Direct cost of material
 - Direct cost of manpower
 - Non-direct cost of factory overhead
- Determination of **domestic component**:
 - Country of origin of material
 - Ownership of the facilities and equipment
 - Citizenship of the manpower
- **R&D cost** can be assessed in TKDN, with term and condition:
 - R&D cost was counted in production cost and distributed to each product price
 - R&D was conducted in Indonesia, and was proven with:
 - ✓ Certificate in Intellectual Property Right
 - ✓ Invoices of R&D cost (product/technology definition, design, prototype, system test and integration, and production preparation)



BMP : Award for company who invest in Indonesia and:

- empower SMEs through partnership,
- has certificate in HSE Management,
- do community development/CSR,
- provide after-sales service

Each Industry can have different Basic Value and Calculation Procedures of TKDN

(depend on the characteristics of the industry)

For example : Electronics and Telematics (ICT) Industry

- Regulation of Minister of Industry No. 69/2014 : Provision and Procedures for Calculation of Local Content Rate (TKDN) in Electronics and Telematics Industry
 - TKDN = TKDN in Manufacturing Process (80%) + TKDN in Design House (20%)**
 - TKDN in Design House refers to**
 - Intellectual Property Right (Patent, Design, Copyright, and Brand) and material; or**
 - Project Base (material, personnel, working equipment, manpower, supporting service)**
- Regulation of Minister of Communication and Informatics No. 27/2015 : Technical Requirements for Telecommunication Equipments with Long Term Evolution (LTE) Technology
 - Minimum TKDN for telecommunication devices with long term evolution (LTE) technology :**
 - 30% for Base Station**
 - 20% for Subscriber Station**

Progress Report of TKDN in Pharmaceutical Industry (Presidential Instruction No. 6/2016)

1. Establish the working groups according to the tasks of Ministry of Industry in Presidential Instruction No. 6/2016
2. Focus Group Discussion about TKDN in Pharmaceutical Industry, with Ministry of Health, pharmaceutical industries, and PT. Surveyor Indonesia
3. Determine the priority drugs that will be calculated for TKDN (in coordination with Ministry of Health)
4. Facilitate the calculation and certification of TKDN in pharmaceutical industries (in order to determine the Basic Value and Calculation Procedures of TKDN in Pharmaceutical Industry) → schedule in 2016 for 70 product, postponed to 2017 due to point 3.

*Thank
You*

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