Knowledge Empowers Business – Forum 2025

A Workshop on Compliance and Global Market Access

Health Supplements Registration in Republic of Indonesia

Jingjiang, Jangsu, 10/11 July 2025


INSPIRY INDONESIA KONSULTAN
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OPERATIONAL PERMIT
PRODUCT REGISTRATION
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INTRODUCTION

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Speaker
apt. Syifa Amirta Sani, S. Farm.
Director of Partnership & International Relations
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Syifa has developed her career within the healthcare sector fields. Her experiences include the feasibility business projects and regulatory support. She handled more than 100++ for licensing and product registration projects.

Her concentration includes business development, international partnerships, and healthcare innovation.

DISCUSSION AGENDA

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REGULATORY BACKGROUND

SUBSTANCES

DOCUMENT REQUIREMENTS

APPLICATION PROCEDURES

REGULATORY BACKGROUND

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Health supplements are products intended to complement nutritional needs, maintain, improve, and/or restore health functions, have nutritional value and/or physiological effects, and contain one or more ingredients such as vitamins, minerals, amino acids, and/or other non-plant substances that may be combined with plant-based ingredients.

- **Indonesian FDA Regulation No 32 Year 2022** *Indonesian FDA Regulation No. 32 of 2022*
- **Kriteria dan Tata Laksana Registrasi Suplemen Kesehatan** *Criteria and Procedures for Health Supplement Registration*

In Indonesia Dietary Supplements shared the same fundamentals regulations with Health Supplements

→

- Safety
- Quality
- Efficacy
- Labeling

IMPORTANT NOTES

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List of Vitamins, Minerals, Amino Acids, and Other Substances Permitted for Use in Health Supplements with Restriction

No.	Substance	No.	Substance	No.	Substance	No.	Substance
1	Vitamin A	9	Biotin	17	Folic Acid	25	Calcium
2	Vitamin B1 (Thiamine)	10	Boron	18	Phosphorus	26	Chromium
3	Vitamin B2 (Riboflavin)	11	Vanadium	19	Iodine	27	Magnesium
4	Vitamin B6	12	Vitamin D	20	Nicotinic Acid	28	Manganese
5	Vitamin B12	13	Potassium	21	Vitamin E	29	Molybdenum
6	Vitamin C	14	Zinc	22	Pantothenic Acid		
7	Vitamin K	15	Nicotinamide	23	Beta-Carotene		
8	Iron	16	Copper	24	Selenium		

IMPORTANT NOTES

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Some of prohibitions (96 plants); 5 animals, 5 types of minerals

No	Plant Name (Species)	Common Name	Prohibited Parts	Simplified Name
1	*Abrus precatorius* L.	Saga	Seed	*Abri Precatorii Semen*
2	*Aconitum* spp.	Aconitum	Entire plant	*Aconiti Herba* and *Aconiti Radix*
3	*Actaea racemosa* L. Syn. *Cimicifuga racemosa* (L.) Nutt.	Black Cohosh	Rhizome and root	*Actaeae Racemosae Rhizoma* and *Actaeae Racemosae Radix* (syn. *Cimicifugae Racemosae Rhizoma* and *Cimicifugae Racemosae Radix*)
4	*Adonis vernalis* L.	Adonis	Entire plant	*Adonis Vernalidis Herba* and *Adonis Vernalidis Radix*
5	*Antiaris toxicaria* Lesch.	Upas	Latex	*Antiaris Toxicariae Latex*
6	*Arcangelisia flava* (L.) Merr.	Yellow wood, yellow root	Wood	*Arcangelisiae Flavae Caulis*

REGISTRATION CATEGORY

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Category 1

Single active ingredients in the form of **vitamins or minerals** whose safety and efficacy profiles are already known.

Category 2

Single active ingredients other than vitamins and minerals or **combinations** whose safety and efficacy profiles are already known.

Category 3

a. new single active ingredients or combinations;
b. new posology;
c. new claims;
d. new dosage forms; or
e. safety and efficacy profiles that are not yet known.

Category 4.

New Imported Registration,

IMPORTANT NOTES

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Animal based

- Bufo gargarizans Cantor, Bufo melanostictus Schneider, Bufo vulgaris Lour (Samsu, Asian toad)
- Parathyroid gland, adrenal gland, thyroid gland, pineal gland (pituitary gland), thymus gland, posterior pituitary, anterior pituitary, ovary, pancreas, testis, placenta, hormones.
- Lytta vesicatoria (Spanish fly)
- Mylabris phalerata Pall
- Mylabris cichorii Linnaeus
- Animals protected under Indonesian government regulations.

Minerals

Lead Compounds: Litharge / lead oxide and inium / red lead / lead tetraoxide

Arsenic Compounds:

- Arsenic trioxide
- Arsenic trichloride
- Orpiment (arsenic trisulfide)
- Realgar

Mercury Compounds:

- Calomel / mercurous chloride
- Sublimate / mercuric chloride
- Cinnabar / mercury sulfide

Sulfur, except for external (topical) medicines.

DOCUMENT REQUIREMENTS

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LEGAL ENTITY / PRE - REGISTRATION

- Tax Identity
- Letter of Authorization valid for three (3) years minimum
- Certificate of Free Sales (should be legalized/apostilled)
- Good Manufacturing Practices (according to the dosage form, valid for one (1) year, issued by the authority)
- Master Formula
- Document Authenticity Declaration Letter

46441 Wholesale of Pharmaceutical Products for Human Use (Traditional Medicines, Health Supplements & Quasi Drugs)

46442 Wholesale of Traditional Medicines for Human Use (Traditional Medicines, Health Supplements & Quasi Drugs)

46334 Wholesale of Non-Alcoholic Beverages Excluding Milk (Health Supplements)

46339 Wholesale of Other Food and Beverages (Health Supplements)

47999 Retail Trade Not in Stores, Stalls, Street Vendors, and Markets n.e.c. (Traditional Medicines, Health Supplements & Quasi Drugs)

DOCUMENT REQUIREMENTS

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ADMINISTRATIVE DOCUMENTS

- Statement Letter from the Responsible Pharmacist at the importer
- **Letter of Appointment** from the manufacturer abroad, granting agency and registration rights, valid for at least 3 years at the time of application
- **Certificate of Free Sale (CFS)** or Certificate of Pharmaceutical Product (CPP) or an equivalent valid document
- **Good Manufacturing Practice (GMP)** Certificate according to the dosage form issued by the competent authority in the country of origin, or an equivalent to Indonesia's GMP
- **Inspection Report** from the past two years issued by the competent authority in the country of origin, if the GMP certificate does not state its validity period
- Contract Agreement Document if the product is manufactured under a contract

DOCUMENT REQUIREMENTS

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TECHINICAL DOCUMENTS

Formula
a. Detailed formula for each dosage form/serving, listing the name, quantity, and function of each ingredient (active and excipient).
b. Source of each active ingredient.
Manufacturing Process
a. Planned batch size (e.g., Capsules: 1,000,000 capsules @ 300 mg).
b. Quantity of each ingredient used per batch, expressed in weight/volume units.
c. Step-by-step manufacturing procedures from raw material preparation to finished product, based on Standard Operating Procedures (SOPs), with clear and detailed descriptions, especially for critical steps.
d. Equipment or machinery used.
Raw Material Sources
a. Specify the manufacturer/supplier of each raw material.
b. Indicate the origin of raw materials derived from animals.
c. Describe the manufacturing process for animal-derived raw materials.

DOCUMENT REQUIREMENTS

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TECHINICAL DOCUMENTS

Raw Material Quality Assessment
a. Provide raw material specifications and reference standards; and/or
b. Results of raw material quality testing.
Packaging Specifications
Finished Product Quality Assessment
a. Finished product specifications and reference standards.
b. Testing methods.
c. Product quality test results.
d. Test results from an accredited laboratory in Indonesia (required for imported products).
Stability Testing of Finished Product
a. Stability protocol, including: batch number, storage conditions, testing schedule, types of tests, estimated sample quantity.
b. Minimum test results from 2 batches stored at 30±2°C, RH 75±5% until expiry date, or results for 6 months under same conditions plus accelerated testing at 40±2°C, RH 75±5% for 6 months, along with a stability commitment.
c. Periodic testing (e.g., at 0, 3, 6, 9, 12, 18, 24 months, etc.) with results presented in table format.
d. Stability conclusion signed by the production manager or authorized person.

DOCUMENT REQUIREMENTS

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TECHINICAL DOCUMENTS	**Source of Specific Materials** Must attach source documentation for specific materials in accordance with applicable regulations, e.g.: a. Capsule gelatin source. b. Halal certificate for capsules. c. BSE-free certificate for bovine-derived gelatin. **Toxicity test results** for products with unknown safety profiles; **Pharmacodynamic and/or clinical test results** for products with unknown efficacy profiles.

DOCUMENT REQUIREMENTS

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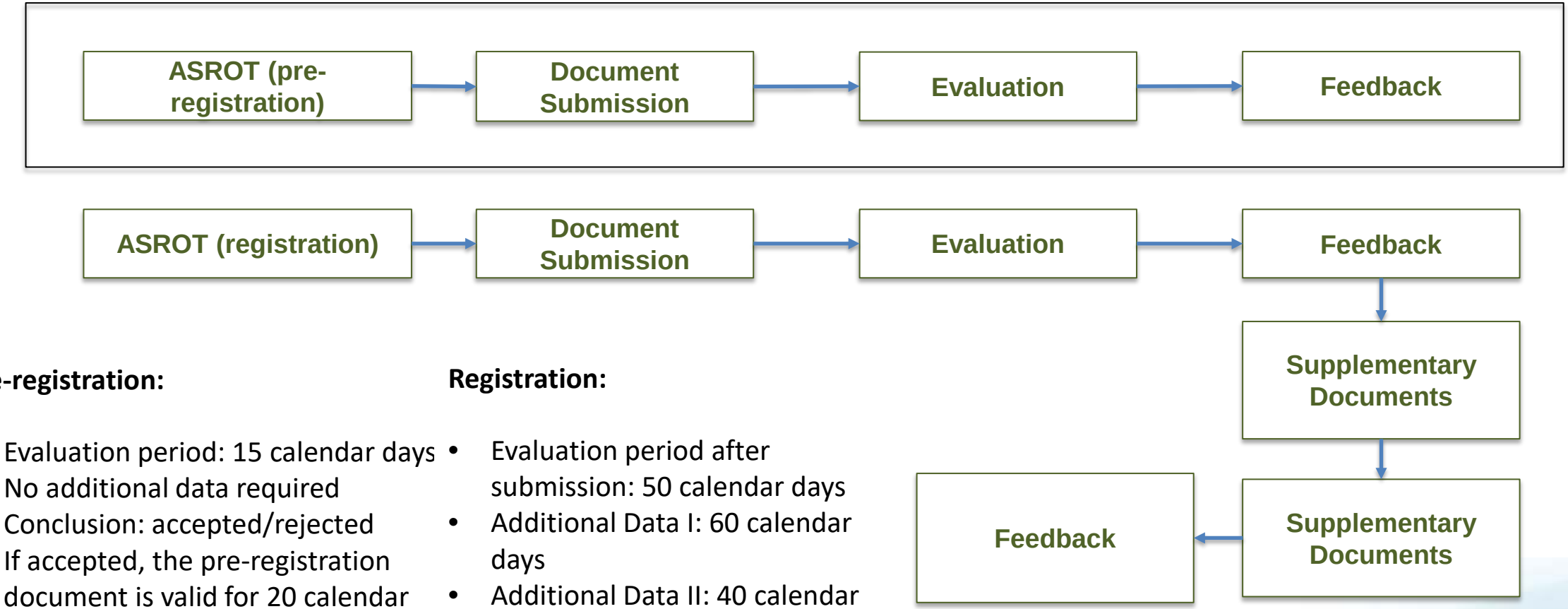

Pre-registration:

- Evaluation period: 15 calendar days
- No additional data required
- Conclusion: accepted/rejected
- If accepted, the pre-registration document is valid for 20 calendar days

Registration:

- Evaluation period after submission: 50 calendar days
- Additional Data I: 60 calendar days
- Additional Data II: 40 calendar days

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THANK YOU

Any Questions?

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For More Info
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Thursday, July 10 – Morning Session: Thailand and ASEAN

Time	Topic	Speaker(s)	Notes
09:00–09:30	**Opening Remarks & Agenda Overview**	ALAND Group Siam Trade Development	ASEAN context, Thailand market positioning
09:40–10:10	**Geopolitical Landscape and Tariffs**	ALAND Group Siam Trade Development	China–US–EU, RCEP, FTAs, Preferential Rules of Origin
10:10–11:10	**Thai FDA Regulatory Framework – Food & Supplements**	**Diego Sala** **Nitwaree Kanjanasurakit**	Definitions, ingredient types, registration, export
11:10–11:50	**Local Manufacturing Strategies & Export from Thailand**	Diego Sala	BOI, company setup, Thai Foreign Business Act – Case Study: Vitamin C market

Thursday, July 10 – Afternoon Session: Russia & ASEAN

Time	Topic	Speaker(s)	Notes
13:00–13:40	**Regulatory Framework in Russia**	**Irina Shchemerova** Siberian Wellness	Russian Local vs. export regulation Europe, Vietnam, Thailand comparison
13:40–14:10	**ASEAN Focus – Indonesia**	**Syifa Amirta Sani** Inspiry Indonesia Konsultan	Indonesian Key regulations, harmonization
14:10–15:00	**ASEAN Focus – Malaysia & Singapore**	**Melisa Leeau** TT Medical Management	Malaysia and Singapore: Product registration, ASEAN gaps
15:00–17:00	**Round Table and Team Outing**	-	-

Friday, July 11 – Morning Session: USA and TARIFF MITIGATION

Time	Topic	Speaker(s)	Notes
09:00–11:00	**Introduction to US FDA Regulations**	**US Regulatory Team** (remote)	USA Import/export, registration, claims, enforcement
11:00–12:00	**US Tariff Mitigation Strategies (Panel)**	**Diego Sala** invited panelists	First Sale, FTZs, Binding Rulings, Q&A

Friday, July 11 – Afternoon Session: MEDICAL DEVICES: CHINA and ASEAN

Time	Topic	Speaker(s)	Notes
13:00-14:00	**Introduction to China NMPA – VMS**	**Aland** VMS Regulatory Team	XBEC, registration, licensing for vitamins, minerals, supplements
14:00–15:00	**Introduction to China NMPA – Medical Devices**	**Jland** Collagen Type III team	Medical-grade supplements, borderline classifications, recombinant collagen
15:00–16:30	**Medical Devices & ASEAN Outlook**	**15:00 Nipapat Phuakyod** **15:30 Anggita Septiani** **16:00 Melisa Leeau**	Focus on injectable products, regulatory comparison TH/ID/MY
16:30	**Final Regulatory Remarks & Q&A**	**Diego Sala**	Summary discussion and participant questions