# The Pharma Legal Handbook

# Indonesia

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

# Indonesia

**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Indonesia.**
**It is a must have for any company operating in the country or looking to enter the market.**

**Prepared in association with Ali Budiardjo, Nugroho, Reksodiputro (ABNR), a leading indonesian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.**



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As Indonesia's longest-established law firm (founded 1967), ABNR pioneered the development of international commercial law in the country following its reopening to foreign investment after a period of isolationism in the early 1960s.

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We offer particular expertise in the Pharmaceuticals & Life Sciences sector, and count among our clients many of the largest multinational companies in the pharma, biotech, medical devices, diagnostics, veterinary and healthcare industries, whom we advise on such aspects as M&A, FDI, licensing & regulatory, capital markets and finance, product liability, halal compliance, and dispute resolution.

With over 100 lawyers, ABNR is the largest independent, full-service law firm in Indonesia and one of the country's top-three law firms by number of fee earners, which gives us the scale needed to simultaneously handle even the largest and most complex transnational deals across a range of practice areas.

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In ABNR, she is part of the teams which handle general corporate, investment, capital market, pharmaceutical and health care, and mining matters. She has also taken part in a number of major transactions and various legal due diligence for acquisition purposes.

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# 01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

**1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?**

The regulatory authorities with specific jurisdiction over drugs, biologicals, and medical devices in Indonesia are:

a. Ministry of Health of the Republic of Indonesia (Kementerian Kesehatan Republik Indonesia, "MOH"); and

b. Indonesia National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan "BPOM").

**2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?**

The basic regulation on health (including drugs, biologicals, and medical devices) is Law No. 36 of 2009 on Health ("Health Law"), as amended by Law No. 11 of 2020 on Job Creation ("Omnibus Law").

### DRUGS AND BIOLOGICALS

- **Authorization**

The authorization of drugs and biologicals is primarily regulated under BPOM Regulation No. 1010/MENKES/PER/XI/2008, as amended by BPOM Regulation No. 1020/MENKES/PER/XII/2008 on Drug Registration. Further, details on the requirements, criteria, category, as well as registration procedures of drugs and biologicals are further regulated under BPOM Regulation No. 24 of 2017 on Criteria and Management of Drug Registration, as last amended by BPOM Regulation No. 13 of 2021 ("BPOM Regulation 24/2017").

Worthy of note is that at the end of June 2018, the Indonesian government launched the Online Single Submission ("OSS") system, which serves as the main gateway for business licensing for the licenses previously handled by different line ministries, regional governments, and quasi-government bodies, including the Ministry of Investment/ Indonesian Direct Investment Coordinating Board (Badan Koordinasi Penanaman Modal or "BKPM"). The Indonesian government is continuously upgrading the OSS system, lastly into a Risk-Based Approach ("RBA") OSS system as the implementation of Government Regulation No. 5 of 2021 on Risk-Based Business Licensing ("GR 5/2021"). The RBA OSS system is effective since August 2021.

GR 5/2021 has introduced a new paradigm in permits and licenses; company licenses are now determined by a risk-based analysis. The risk assessment is classified into 4 levels: Low, Medium-Low, Medium-High and High, each with its own characteristics, and assessed using various criteria, including safety, health, the environment, resource utilization and management. GR 5/2021 generally sets out the risk-level, validity, requirements, obligations, and timeline related to the licensing. Higher risk imposed higher license requirements.

All licenses and permits must be applied for through the OSS system, including licenses related to drugs and biologicals. Although, in some cases, verification and assessment by the relevant ministries are still required.

• **Pricing**

Pharmaceutical industries in Indonesia are required to provide information on the highest retail price on the relevant drug's label under MOH Regulation No. 98 of 2015 on the Provision of Information on Highest Drug Retail Price ("MOH Regulation 98/2015"). The MOH Regulation 98/2015 also grants authorization to the MOH to determine from time to time the retail price of generic drugs that are not included in the e-catalogue (an electronic system on procurement of goods/services by government).

### MEDICAL DEVICES

• **Authorization**

The authorization of medical devices is primarily regulated under MOH Regulation No. 62 of 2017 on MA of Medical Devices, In Vitro Diagnostic Medical Devices, and Household Health Products ("MOH Regulation 62/2017").

Upon the launch of the RBA OSS system, the risk-level, validity, requirements, obligations, and timeline related to the licensing of medical devices are as regulated under GR 5/2021.

• **Pricing**

There is no specific regulation on the pricing of medical devices.

There is no regulation on reimbursement of drugs, biologicals, and medical devices in Indonesia. The Government, however, manages a public healthcare system via an independent authority. Please refer to Question No. 10 below.

**3. What are the steps to obtaining authorization to develop, test, and market a product?**

### DRUGS

Marketing Authorization ("MA") of drugs, including imported drugs, must be obtained by Indonesian pharmaceutical manufacturing companies.

The Development and testing of drugs differs between generic and new drugs. For generic drugs, applicants may conduct development of formula/testing in the laboratory without any authorization. Once the applicant is sure of the result of the development/testing, the applicant must register the drugs and obtain an MA.

Development and testing of new drugs, on the other hand, must adhere to the regulations on pre-marketing clinical trials. If the new drugs are to be imported from overseas (meaning that they are already marketed and distributed overseas but not in Indonesia), the development and testing may be conducted overseas. The BPOM will accept result of clinical and non-clinical trials conducted overseas as part of the MA application as below.