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Distributing Medical Devices in Indonesia

As the fourth-most populous country in the world, Indonesia faces many challenges in providing sufficient healthcare services to its nearly 280 million citizens. Among these challenges is a scarcity of medical devices, especially in rural areas. This makes Indonesia a promising market for medical device distribution businesses.

If you are considering distributing medical devices to Indonesia, this article provides a brief overview of the applicable regulatory requirements.

The importing and distribution of medical devices in Indonesia is regulated under Ministry of Health Regulation No. 60 of 2017 on the Supervision of Trade Management for the Import of Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies ("**MOH Reg. 60/2017**") and Ministry of Health Regulation No. 62 of 2017 on Distribution Licenses for Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, as amended by Ministry of Health Regulation No. 26 of 2018 ("**MOH Reg. 62/2017**"). Under MOH Reg. 62/2017, a distribution license is required for the relevant medical devices. The distribution license for imported medical devices can only be applied for by:

i. a sole agent/sole distributor/exclusive distributor;
ii. a medical device distributor with an appointment letter from the principal and a Power of Attorney to register the medical devices in Indonesia;
iii. a medical device distributor with an agreement with the manufacturer;
iv. a medical device distributor that assembles the devices; or
v. a medical device distributor that repackages them.

Furthermore, MOH Reg. 62/2017 specifies that one medical device sold under one brand or trade name from certain manufacturer can only be distributed by one distributor/importer. For example, if a medical device from Manufacturer X under the brand "IndoHealth Plus" has been distributed in Indonesia by Company A, the Company B cannot also distribute the same medical devices in Indonesia.

Under MOH Reg. 62/2017, medical devices may only be imported by a company that holds a medical device distributor's license (*Izin Penyalur Alat Kesehatan*) and a distribution license (*Izin Edar)* for the imported medical devices. This is in line with MOH Reg. 60/2017 which requires medical devices to be imported by a medical device distributor with a distribution license for the relevant devices. Given these provisions, it can be inferred that the importer of a medical device must also be the distributor of the relevant medical device.

To import and distribute medical devices in Indonesia, a foreign investment company ("**PMA Company**") can be established to engage in the medical device distribution business. Under the current investment regime, this business is open to 100% foreign investment.

There is a general rule in Indonesia that foreign investment companies engaged in distribution must appoint a local distributor (wholly owned by local shareholders) to distribute the products to retailers. However, this requirement does not apply to companies distributing medical devices. Therefore, a PMA Company engaged in medical device distribution can directly distribute its products to customers, such as hospitals, clinics, and other health service facilities, without needing a local distributor.

Entering Indonesia's medical device market may take time in setting up the appropriate investment and distribution framework, but with the right guidance and groundwork, the rewards can be considerable, while also contributing to improved healthcare.

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