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New Minister of Health Regulation on Marketing Authorization for Medical Devices, *In Vitro* Diagnostic Medical Devices and Household Medical Supplies

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On 29 December 2017, the Minister of Health ("**MOH**") issued Regulation No. 62 of 2017 on Marketing Authorization for Medical Devices, *In Vitro* Diagnostic Medical Devices and Household Medical Supplies ("**Regulation 62**"), which became effective on the date it was issued.

Regulation 62 revokes MOH Regulation No. 1190/MENKES/PER/VIII/2010 on Marketing Authorization for Medical Devices and Household Medical Supplies (*Peralatan Kesehatan Rumah Tangga* or "**PKRT**") ("**Regulation 1190**").

Regulation 62 was issued to harmonize Indonesian regulations with ASEAN and global level regulations which govern medical devices and PKRT.

Below are notable new features provided under Regulation 62.

In Vitro Diagnostic Medical Device

Under Regulation 1190, *in vitro* diagnostic devices were already considered as part of the medical device group (under Article 3 point g to be precise).

Regulation 62 simply emphasizes this and re-classifies *in vitro* diagnostic devices as a more specialized group of medical devices.

Regulation 62 also provides a clearer scope on which products are considered as *in vitro* diagnostic medical devices. Based on Article 1.3 of Regulation 62, *in vitro* diagnostic medical devices means every reagent, reagent product, calibrator, control material, kit, instrument, apparatus, tools or system, either used individually or combined with other reagents, reagent products, calibrators, control material, kits, instruments, apparatus, tools or systems which is expected by its **owner** (please see 'Product Owner' below) to be used by way of *in vitro* for the purpose of examination of each specimen, including blood or tissue which are sourced from human body, which is solely or essentially for the purpose of giving information by taking into consideration the physiological or pathological condition or congenital abnormalities, to determine the safety and properness of each blood or tissue donor with the potential recipient, or to observe therapy measures and to contain specimens (we will refer to *in vitro* diagnostic medical devices as "**IVD**").

Based on Article 7.2 of Regulation 62, IVDs are divided into four classes based on their level of risk:

Class A : Cause low level risk to individuals and communities

Class B : Cause medium level risk to individuals and low level risk to communities

Class C : Cause high level risk to individuals and medium level risk to communities.

Class D : Cause high level risk to individuals and communities

Separation on the Concept of Principal, Product Owner, Foreign Manufacturer and Local Manufacturer

Regulation 62 finally makes a clear distinction between the concepts of 'Local Foreign Manufacturer', 'Foreign Manufacturer', 'Principal' and 'Product Owner':

(a) Based on Article 1.7 of Regulation 62, '**Local Manufacturer**' (*Produsen*) means a company in the form of a business entity that has a production certificate to **manufacture** (please see below), including to assemble and/or repackage medical devices, IVDs and PKRTs **locally**.

Based on Article 1.6 of Regulation 62, '**Manufacturing**' means activities of making, processing, packaging and/or assembling to produce medical devices, IVDs and PKRTs.

(b) Based on Article 1.8 of Regulation 62, '**Foreign Manufacturer**' (*Pabrikan*) means **foreign companies** that produce medical devices, IVDs and PKRTs which have fulfilled quality management system.

(c) Based on Article 1.9 of Regulation 62, '**Principal**' means Foreign Manufacturer or foreign representative which is appointed and given authority by the Foreign Manufacturer or Product Owner to appoint a medical device wholesaler (*Penyalur Alat Kesehatan* or "**PAK**") or a PKRT importer in Indonesia.

(d) Based on Article 1.10 of Regulation 62, '**Product Owner**' is a company in the form of a legal entity or business entity which is the owner of the formula, design, trade name or trademark.

The introduction of the foregoing terms offers more depth to each provision under Regulation 62. While most of the contents of Regulation 62 are similar with Regulation 1190, the above concept allows us to get a clearer understanding of which party is being referred to in each of the provisions in the regulation.

For instance, under Article 15 of Regulation 62, a Local Manufacturer cannot register imported products that are having the same type as products that the Local Manufacturer produces. In Regulation 1190, this requirement exists but with a rather unclear scope, ie, it is directed to any medical device company.

Marketing Authorization Holder

Regulation 62 expanded the range of eligible parties who can hold marketing authorization for medical devices and PKRTs.

The significant new feature is the introduction of the concepts of original equipment manufacturer (or "**OEM**"), contract manufacturing (or "**Makloon**"), sole agent/sole distributor/exclusive distributor (or "**SA/SD/ED**"), 'reassembling' and 'repackaging':

(a) Based on Article 1.13 of Regulation 62, 'Makloon' means delegation of part or the whole of the manufacturing process of medical devices, IVDs or PKRTs from a Local Manufacturer that is also a Product Owner that holds a production certificate to another Local Manufacturer that holds a production certificate.

(b) Based on Article 1.14 of Regulation 62, 'OEM' is a production activity that is done by a Local Manufacturer/Foreign Manufacturer based on the request of a PAK or PKRT company as the Product Owner using the trademark from the Product Owner.

(c) Based on Article 1.15 of Regulation 62, 'SA/SD/ED' means PKRT importers and PAKs that are appointed by Local Manufacturer or Foreign Manufacturer or Principal as their representative to register and distribute medical devices, IVDs and PKRTs in Indonesia and to provide after sales services of the medical devices, IVDs and PKRTs whereby the appointment is done based on an order or grant of authority with limitation on certain authorities for them to act for and on behalf of the Local Manufacturer, Foreign Manufacturer or Principal.

(d) Based on Article 1.16 of Regulation 62, 'Assembling' means a series of actions to form medical devices, IVDs and PKRTs from dissembled products, half-finished products and/or products with constituent components sourced from local and/or imported components.

(e) Based on Article 1.17 of Regulation 62, 'Repackaging' means a series of production activities, which includes wrapping, labelling and tagging (*penandaan*), without changing the basic ingredient/formula, specification and use of the product.

We set out below the list of eligible parties that can apply for and hold marketing authorization for locally manufactured and imported medical devices, IVDs and PKRTs based on Regulation 62:

Locally manufactured	• Local Manufacturers • Local Manufacturers who gave Makloon • Local Manufacturers who carry out Assembling • PAKs that are also Product Owners that have a cooperation agreement with Local Manufacturers - ***Note****: this point is not applicable for the application for marketing authorization for PKRT*. • Local Manufacturers that manufacture medical devices, IVDs and PKRTs that carry out OEM.
Imported	• SA/SD/EDs • PAKs (for medical devices and IVDs) or PKRT importers (for PKRTs) that have an appointment letter from a Foreign Manufacturer or a Principal and have been granted an authority to register the medical device, IVD and PKRT in Indonesia • PAKs (for medical devices and IVDs) or PKRT importers (for PKRTs) that are also Product Owners that have a cooperation agreement with Foreign Manufacturers • PAKs that carry out Assembling • PAKs that carry out Repackaging

Some things to be considered:

1. For locally manufactured products, Local Manufacturers that carry out Assembling may apply for and obtain the marketing authorization, provided that they meet the following criteria:
   (a) Components that have a major function in the finished product are locally manufactured.
   (b) There must be more locally sourced components than imported (or foreign) components.
   (c) The Manufacturing process must be mostly done locally.
2. For imported products, PAKs that carry out Assembling and Repackaging must fulfill the following criteria:
   (a) Hold a production certificate
   (b) Hold a power of attorney from the Foreign Manufacturer

Resale of Products by Marketing Authorization Holder

Notwithstanding the foregoing, Regulation 62 does not clearly mention whether the holder of the marketing authorization **must** resell the products. This is one of the major issues with Regulation 1190 that has not been addressed under Regulation 62.

When Regulation 1190 was still in effect, the MOH verbally confirmed its position many times, ie, that the marketing authorization holder must resell the products that are registered under the marketing authorization that it holds.

Based on how Regulation 62 is drafted, the requirement to resell products is only clear if the marketing authorization is held by SA/SD/EDs. The definition clearly mentions that the scope of the appointment of the SA/SD/EDs also includes the resale of the products by them.

Limitation on Agency

Based on Article 13 of Regulation 62, every medical device, IVD and PKRT that has one trade name or trademark that originates from a Foreign Manufacturer or Principal can only have one PAK (for medical devices and IVDs) and one PKRT importer (for PKRT) as its agent.

Further, based on Article 15.3 of Regulation 62, PAKs and PKRT importers that carry out OEM locally are prohibited from registering medical devices, IVDs and PKRTs that have the same type and specification as the medical devices, IVDs and PKRTs that they carry in their agency.

However, Regulation 62 does not provide any further clarity on what 'agent' or 'agency' really means here, ie, whether this means that the PAKs and PKRT importers will not sell the products.

Requirement to Provide Certificate of Free Sales (CFS) for Imported Products

Regulation 62 clearly stipulates that for now all applications for marketing authorization for imported medical devices, IVDs and PKRTs must also be accompanied by a Certificate of Free Sales ("**CFS**") issued by the authorized authorities in the health care sector in the originating country of the product.

If the authorities from the country of origin of the medical devices, IVDs and PKRTs cannot issue a CFS, the applicant must seek a CFS from a government authority that handles health care matters in another country that can issue a CFS. If the products are not registered in their country of origin, then the CFS can be issued by other authority in the originating country.

The CFS must at least contain the following information:

(a) trade name or trademark

(b) type of product

(c) name and address of Foreign Manufacturer

(d) validity period (of the CFS)

Limitation on the Registration of Similar Products

As mentioned above, Local Manufacturers are prohibited from registering imported products that are similar to what they produce.

Based on Article 15.1 of Regulation 62, if imported medical devices, IVDs or PKRTs have the same type as but different specifications from the products that a Local Manufacturer produces, the products can be registered by Local Manufacturers that are affiliated with the Foreign Manufacturer of the products.

Online Application System

Regulation 62 shows an effort from the government to push to have applications for marketing authorization done online.

Based on Article 18 of Regulation 62, all applications for new registration is now done online through the Indonesian National Single Window ("**INSW**") system or website with the address: regalkes.kemkes.go.id.

Further, Article 22 of Regulation 62 also provides that marketing authorization is now issued electronically. This provision provides the legal basis for electronic copies of marketing authorizations to have the same validity as physical licenses. Applicants or other parties that might have an interest may print out the electronic file of the marketing authorization through the INSW system or the MOH's website: regalkes.kemkes.go.id.

In the event of force majeure, the marketing authorization may be issued manually or through physical form. Presumably, one of the reason of this provision is to anticipate if any force majeure caused failure to the electronic system that makes the authorities unable to issue the licenses electronically.

Invalidity of Marketing Authorization

Under Article 25 of Regulation 62, a marketing authorization will be deemed to be invalid due to the following reasons:

(a) The marketing authorization has expired.

(b) The production certificate has expired and/or is cancelled.

(c) The period of appointment and/or the grant of authority as SA/SD/ED has expired or is not renewed.

(d) The marketing authorization is revoked.

(e) A marketing authorization will also be invalid if the medical device wholesaler license ("**IPAK**") has expired.

Change of Marketing Authorization

Under Article 30 of Regulation 62, the holder of a marketing authorization must submit an application to amend the marketing authorization if the following changes are made to the product:

(a) size

(b) packaging

(c) tagging (*penandaan*)

(d) the accessories/attachment on the marketing authorization

(e) the name and/or address of the representative who has authority from the Foreign Manufacturer

The amendment of a marketing authorization due to the foregoing reasons will be done without changing the number of the marketing authorization. Any change outside the above mentioned will change the number of the marketing authorization. Therefore, the holder of the marketing authorization must go through a new application process for the marketing authorization to reflect those changes ("**Reapplication**").

Based on Regulation 1190, a change to the Taxpayer Registration Number (*Nomor Pokok Wajib Pajak* or "**NPWP**") was still included as a change that did not change the number of the marketing authorization. Now the MOH must issue a new marketing authorization number if there is a change to the NPWP of the marketing authorization holder.

Destruction of Products

Under Article 59 of Regulation 62, destruction of medical devices, IVDs and PKRTs is done in the following circumstances:

(a) The products do not fulfill the requirement for safety, quality and usefulness.

(b) The products have expired.

(c) The marketing authorization of the products has been revoked.

(d) The products are not manufactured and/or imported in compliance with the prevailing laws and regulations.

(e) The products are connected to a criminal offense.

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