Legal

Legal framework: Yes


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Pharmaceuticals and Devices Agency (PMDA) http://www.pmda.go.jp/english/index.html

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: The term "medical device" as used in this Law refers to medical appliances or instruments (excluding regenerative medicine products) intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure and functions of the bodies of humans or animals, as specified by Cabinet Order. Law (PMD Act) No. 145 (as amended No.50 of 2015) Chapter 1, Art. 4

In vitro diagnostic medical device (IVD) defined: Yes

Text: The term “in-vitro diagnostic” as used in this Law refers to pharmaceuticals intended exclusively for the use in diagnosis of diseases, and which are not directly used in the bodies of humans or animals. Law (PMD Act) No. 145 (as amended No.50 of 2015) Art. 14

Medical device classification

Classification: Yes

Categories: Class I, II, III, and IV.

Classification rules: Yes


Essential principles

Essential principles: Yes

Details: The quality, efficacy and safety of the medical devices or in-vitro diagnostics shall be inspected for the quality, efficacy and safety of the medical devices or in-vitro diagnostics as confirmation specified under Paragraph 3 based on the details of the application. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art.23-2-9 (5)

Conformity assessment

Conformity assessment bodies: Yes

Details: An accredited certification body shall establish rules concerning operations for product inspections (hereinafter referred to as “operational rules”) and apply for license from the Minister of Health, Labour and Welfare before beginning the operations for certification of conformity. The same shall apply when it intends to change the rules. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art.23-10

Pre-marketing / procedure: A person who intends to market medical devices or in-vitro diagnostics must receive approval for each such item. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art.23-2-5; The quality, efficacy and safety of the item shall be examined based on the content of the application for the item concerned and the document specified. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art.23-2-5 (5)

Reliance

Reliance: N/A

Details: N/A

Jurisdictions: N/A
Clinical investigation
Clinical investigation controls: Yes
Details: A person who intends to obtain approval specified shall make an application by attaching data concerning the results of clinical studies and other pertinent data to their applications. When the medical device or in-vitro diagnostic concerned in such application is specified by an Ordinance of the Ministry of Health, Labour and Welfare, the data concerned must be collected and compiled in accordance with standards specified by an Ordinance of the Ministry of Health, Labour and Welfare. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art. 23-2-5 (3)

Registration and listing
Registration of establishment: Yes
Details: A person who intends to be engaged in the business of manufacturing medical devices or in-vitro diagnostics (including designing; hereinafter the same shall apply in this Chapter and Article 80.2) shall receive registration from the Minister of Health, Labour and Welfare (MHLW). Law (PMD Act) No. 145 (as amended No.50 of 2015). Art. 23-2-3
Listing of medical devices: Yes
Details: A holder of marketing authorization for medical devices or in-vitro diagnostics shall, when intending to market medical devices or in-vitro diagnostics notify the Minister of Health, Labour and Welfare thereof for each such item beforehand, pursuant to the provisions of an Ordinance of the MHLW. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art. 23-2-12

Import controls
Import controls: Yes
Details: Manufacturers with no local presence in Japan must appoint a Marketing Authorization Holder (MAH) or a Designated MAH (D-MAH) to manage registration with the PMDA. Law (PMD Act) No. 145 (as amended No.50 of 2015). Article 23-2-19

Post market controls
Post Market Surveillance: Yes
Details: The manufacturer, etc. shall ensure that the products which do not conform to the product requirements are identified and controlled to prevent their unintended use or delivery. Ministerial Ordinance No. 169, Art. 60
Inspection (QMS): Yes
Details: A person who intends to receive approval shall, where the approval relates to medical devices or in-vitro diagnostics shall receive an on-site inspection or a document-based conformity inspection by the MHLW. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art. 23-2-5 (6) (8). Class I, II, III, and IV device manufacturers must implement QMS. When a manufacturer passes a QMS conformity assessment, it is issued a Certificate of QMS Conformity. Ordinance 169.
Enforcement: N/A
Details: The provisions revised by this Law shall also apply to dispositions by an administrative agency prior to the enforcement of this Law, inactions by an administrative agency pertaining to an application filed prior to the enforcement of this Law or other matters that have arisen prior to the enforcement of this Law. Law (PMD Act) No. 145 (as amended No.50 of 2015). Art. 19 (2)
Adverse event reporting: Yes
Details: The manufacturer, etc. shall ensure that, prior to the authorisation and approval of the work instructions, a determination of any adverse effects of the rework upon the products is made and documented. Ministerial Ordinance No. 169, Art. 60.10
Field safety corrective action monitoring: Yes
Details: The manufacturer, etc. shall ensure that, when the planned results specified in paragraph 1 of Article 14 are not achieved, the correction and corrective action shall be taken, as appropriate, to ensure the conformity of the products.Ministerial Ordinance No. 169, 2004, Art. 57.3
The manufacturer, etc. shall take the corrective actions which are appropriate to the effects of the nonconformities encountered to eliminate the cause of the nonconformities in order to prevent the recurrence. Ministerial Ordinance No. 169, Art. 63
Advertising: N/A
Details: N/A
Labelling: N/A
Details: N/A

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.