Pakistan

Legal

Legal framework: Yes
Authorizing legislation: Medical Devices Rules, 2015 http://www.dra.gov.pk/gop/index.php?q=aHR0cDovLzE5Mi4xNjguNzAuMTM2L2RyYXAv

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Medical Devices and Medicated Cosmetics Division, Drug Regulatory Authority of Pakistan http://www.dra.gov.pk/gop/index.php?q=aHR0cDovLzE5Mi4xNjguNzAuMTM2L2RyYXAv

Responsibilities of the NRA: The Medical Devices and Medicated Cosmetics Division is responsible for the assessment, enlistment or registration of medical devices and medicated cosmetics, medicated shampoos and medicated soaps for human beings, animals and to perform other functions connected therewith. http://www.dra.gov.pk/gop/index.php?q=aHR0cDovLzE5Mi4xNjguNzAuMTM2L2RyYXAv

Medical device definition

Medical device defined: Yes
Text: Medical devices are not defined unto themselves; rather, they are defined as “active medical device,” “active device intended for diagnosis,” “active therapeutic device,” “adulterated medical device,” “counterfeit medical device,” “custom-made medical device,” “implantable medical device,” “invasive medical device,” “life supporting or life sustaining medical device,” “medical device for self-testing or self-administration,” “misbranded medical device,” “special access medical device,” “spurious medical device,” “sub-standard medical device,” and “surgically invasive medical device.” Medical Devices Rules, Ch. I, Art 2. The Medical Device Board also registers all devices that fall under the GHTF definition. Medical Devices Rules, Ch. VIII, 86.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined Separately.

Medical device classification

Classification: Yes
Categories: Class A, B, C, and D
Classification rules: Yes
Classification rules details: Classification rules are detailed in the Medical Devices Rules, Ch. VI, Part I.

Essential principles

Essential principles: Yes
Details: N/A

Conformity assessment

Conformity assessment bodies: Yes
Details: Yes
Conformity Assessment Bodies must be registered with the MDB. Medical Devices Rules, Ch. II, Part I, 3. Once satisfied all applicable requirements have been fulfilled, the body will issue a certificate and report of conformity. Id.

Pre-marketing / procedure: The manufacturer must compile evidence of conformity and appoint a conformity assessment body that is registered with the Medical Device Board to conduct conformity assessment. Medical Devices Rules, Ch. II, Part II, 3.

- conformity assessment to register a medical device comprises:
  - conformity assessment of the quality management system
  - conformity assessment of post-market surveillance system
  - conformity assessment of technical documentation
  - declaration of conformity

Medical Devices Rules, Ch. II, Part II, 4.

The manufacturer must certify that its medical device complies fully with essential principles and draw up a declaration of conformity. Medical Devices Rules, Ch. II, Part II, 8.
Reliance

Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation

Clinical investigation controls: N/A
Details: N/A

Registration and listing

Registration of establishment: Yes
Details: The Medical Device Board issues licenses of establishment: (1) license to manufacture medical devices, and (2) license to import medical devices. Medical Devices Rules, Ch. V, 69.

Listing of medical devices: Yes
Details: The Medical Device Board registers medical devices, which include all those as defined by the GHTF definition. Medical Devices Rules, Ch. VIII, 86; see also id. Ch. XVI, 137.

Import controls

Import controls: Yes
Details: The authorized representative must obtain evidence of conformity from its foreign manufacturer. Medical Devices Rules, Ch. II, Part II, 9.
A medical device may be imported so long as the importer (1) possesses a valid medical device establishment license and registration and have proper storage facilities as well as complies with notice requirement. Medical Devices Rules, Ch. IX, 94.

Post market controls

Post Market Surveillance: Yes
Details: The manufacturer must establish, maintain and implement a post-market surveillance system. Medical Devices Rules, Ch. II, Part II, 6.

Inspection (QMS): Yes
Details: The medical device manufacturer must establish, maintain, and implement a QMS to ensure GMP. The extent of the system depends on the class of device to meet conformity requirements. Medical Devices Rules, Ch. II, Part II, 5; see also id., Ch. II, Part II, 10.

Enforcement: N/A
Details: N/A

Adverse event reporting: N/A
Details: N/A

Field safety corrective action monitoring: Yes
Details: A licensee of the Medical Device Board must establish, maintain, and implement an appropriate and effective system of post-marketing surveillance that includes FSCAs. Medical Devices Rules, Ch. XI, 125.

Advertising: Yes
Details: An application must be made to the Medical Device Board to request permission to advertise a medical device. Medical Devices Rules, Ch. XVIII, 139-141.

Labelling: Yes
Details: No person may place a medical device on the market unless it has been appropriately labelled, and no person may conduct a clinical investigation on another unless the appropriate label has been provided. Labels must be in English, but some labels for devices intended for at-home use may be in Urdu. The labels must contain identifying information of the manufacturer, description of use of the medical device, warnings, etc. Medical Devices Rules, Ch. X, 114-120; see also id. Ch. X, 121 (details additional information for the label of an IVD).

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.