Papua New Guinea

World Bank income group: Lower middle income

Legal

Legal framework: Yes
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Pharmaceutical Services Standards Branch, Department of Health http://www.health.gov.pg/pages/pharmaceutical.htm
Responsibilities of the NRA: The Pharmaceutical Services Standards Branch is currently registering medical products, including medical devices, provisionally now according to its website. http://www.health.gov.pg/pages/pharmaceutical.htm

Medical device definition

Medical device defined: Yes
Text: “device” means any instrument, apparatus or contrivance, and includes any component, part or accessory of that instrument; “medical device” means any device–
(a) the sole or principal use of which is, or ordinarily is, a therapeutic use; or
(b) that is represented to be, or might reasonably be taken to be, for medicinal purposes.
Medicines and Cosmetics Act 1999.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification

Classification: N/A
Categories: N/A
Classification rules: N/A
Classification rules details: N/A

Essential principles

Essential principles: N/A
Details: N/A

Conformity assessment

Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: N/A

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: A person shall not, with effect from the appointed day, on any premises, manufacture for sale a product to which this Part applies unless the manufacture by him of that product is authorized by a licence granted. Medicines and Cosmetics Act 1999, Art. 7, 9
Listing of medical devices: Yes
Details: A person may apply to the licensing authority for a product licence. Medicines and Cosmetics Act 1999, Art. 9
Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): N/A
Details: N/A

Enforcement: Yes
Details: A person, who, with effect from the appointed day, imports, manufactures, sells, supplies or otherwise deals with a product without a licence granted under this Part, is guilty of an offence. (Penalty: A fine of not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both) Medicines and Cosmetics Act 1999, Art. 6.2

A person, who sells a product that does not conform to the standard prescribed in relation to that product, is guilty of an offence. Medicines and Cosmetics Act 1999, Art. 15

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

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: Yes
Details: An advertisement for a medical device must include an accurate description of the device, a statement of uses of the device, a statement on appropriate precautions to be taken with the device, and statement of contraindication. Medicines and Cosmetics Regulation, Art. 49.

Labelling: Yes
Details: A label must contain the trade name, the appropriate quantitative particulars, adequate direction for safe use, warnings, the batch number, and the manufacturing license number as well as the name and address of the manufacturer. Medicines and Cosmetics Regulation, Art. 45.

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.