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GHWP Towards Medical Device Harmonization

Introduction to Macao's Medical Device Regulatory System

Government of the Macao Special Administrative Region of the People's Republic of China

Pharmaceutical Administration Bureau (ISAF)

December 12, 2024

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Function of the Pharmaceutical Administration Bureau (ISAF)

Pharmaceutical Administration Bureau (ISAF)

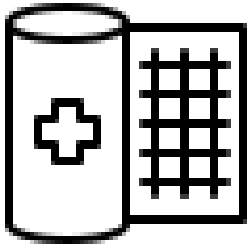
Responsible for the study, planning, coordination, and implementation of policies in the field of pharmaceutical supervision and administration in Macao SAR.

- Pharmaceutical Activities and Drug Registration (including TCM)
- Pharmaceutical Professional Activities
- Medical Device Registration and Activities
- Advertising Activities of Pharmaceuticals and related products

Current State of Medical Device Regulation in Macao

Currently, there is no specialized legal system in Macao to regulate medical devices

In Vitro Diagnostics (IVD)



Gauzes/dressing

catheters/stents

dental/orthopedic adhesives

The Pharmaceutical Administration Bureau

Import into Macao

Only certain medical device categories are subject to import controls

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Strengthening regulatory system

Protect Public Health

Support industry development

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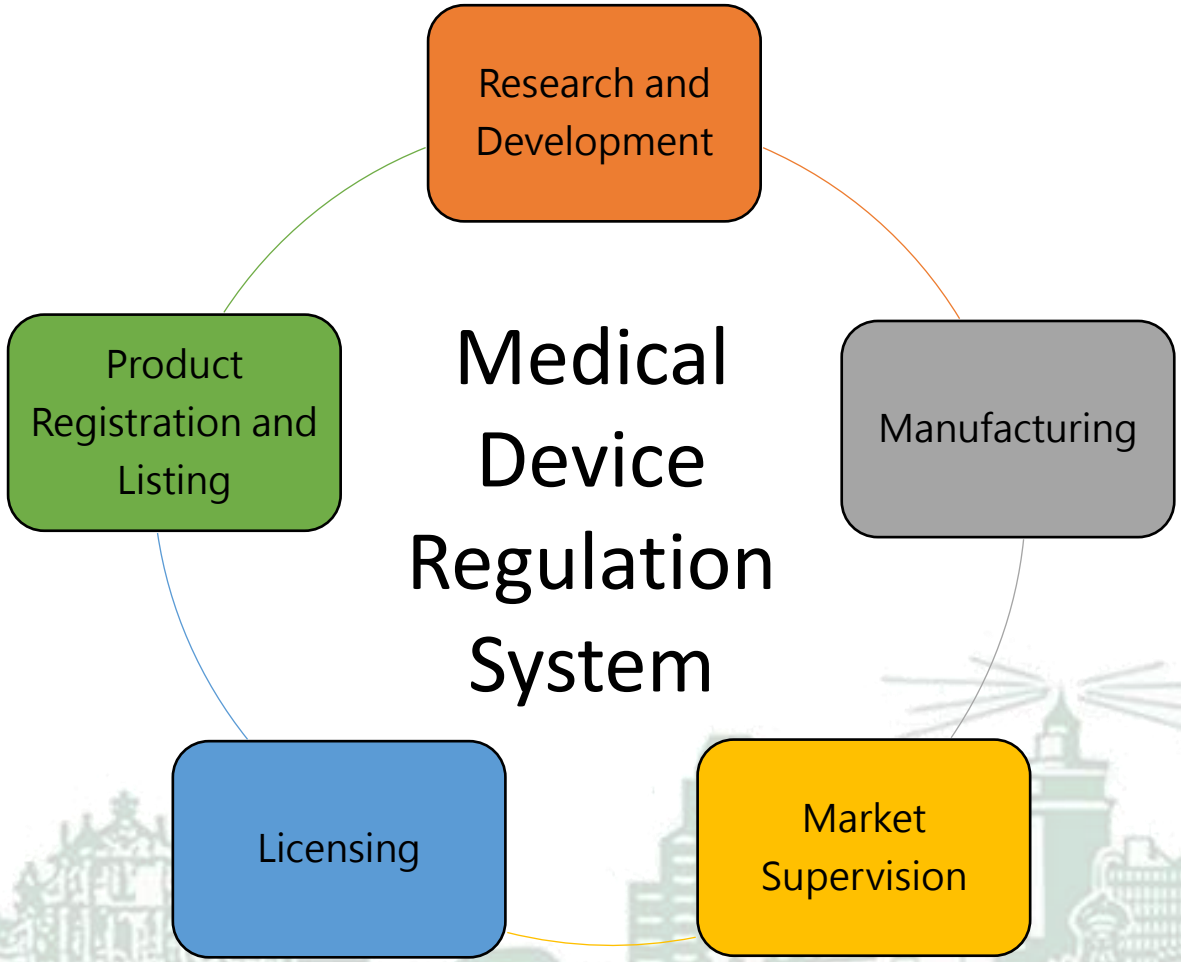
Formulating Macao's First Law on Medical Device Regulation



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Macao's Proposed Medical Device Regulatory Framework

Regulation on the Supervision and Administration of Medical Devices

- Product Registration and Listing
- Licensing and Market Supervision

Main content of Macao's Medical Device Regulation

1. Establish a risk-based classification system for medical devices, categorizing medical devices into three main classes based on their potential risk level, and respectively regulating the registration and listing of medical devices.

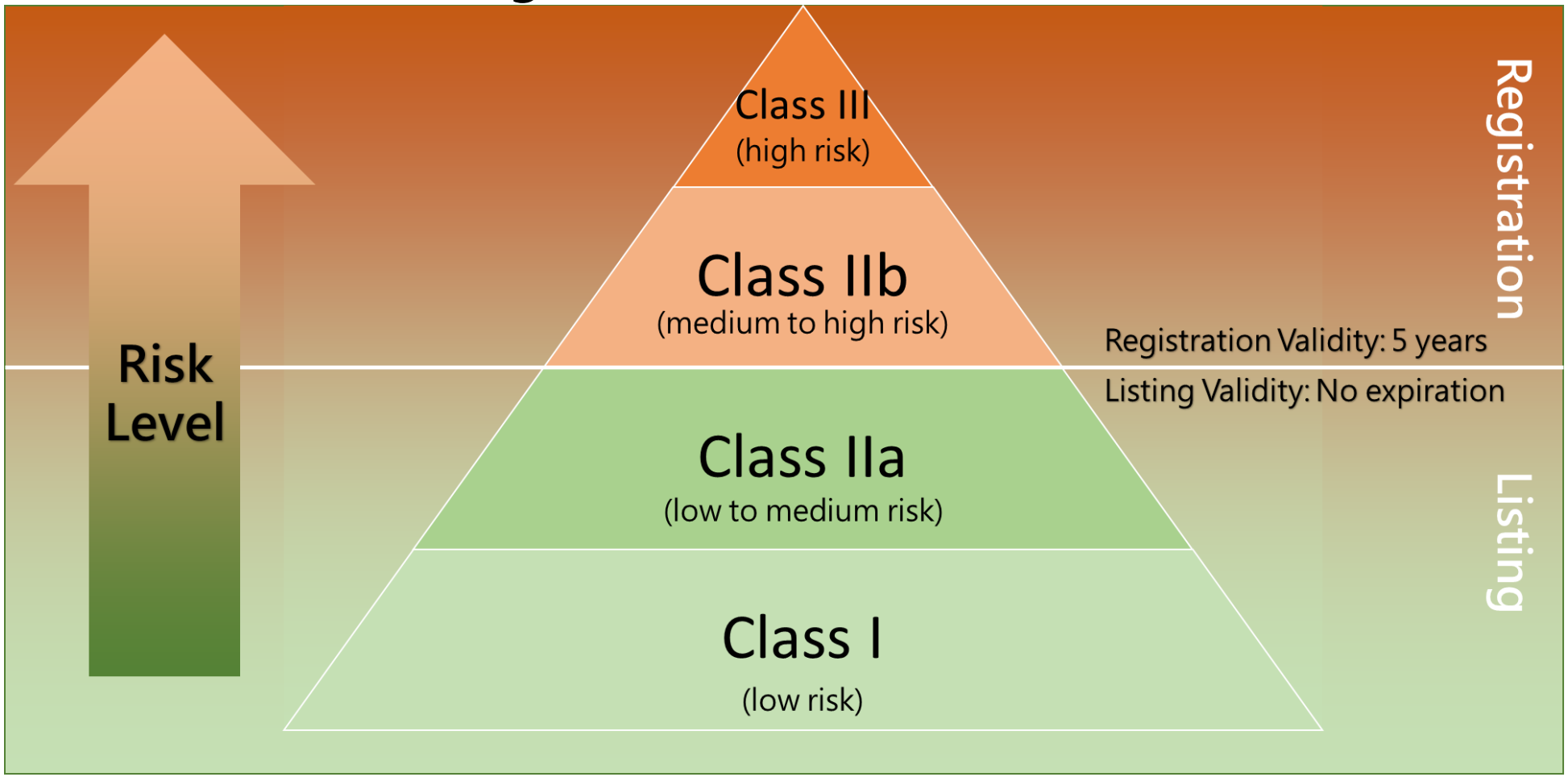
2. Stipulate that the manufacturing, import/export, wholesale, and retail of medical devices in Macao SAR must obtain a "Medical Device Manufacturing License" and a "Medical Device Operating License" respectively.

Main content of Macao's Medical Device Regulation

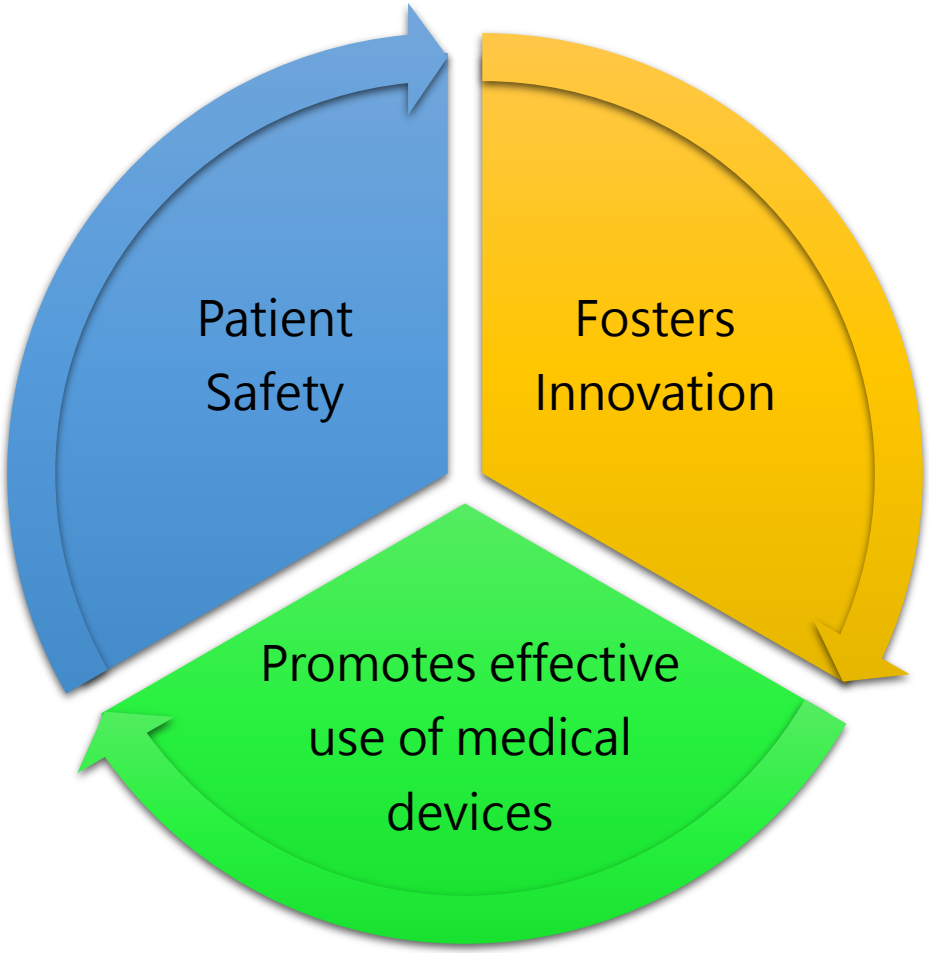
3. Specify the principles that must be adhered to in medical device related activities, clearly designating the Pharmaceutical Administration Bureau as the regulatory authority, and establishing corresponding market supervision and sanctioning systems.

4. Setting transitional provisions for existing medical devices and medical device business entities.

Medical Device Categories



Our Vision - a medical device regulation that prioritizes:



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Our Vision – by joining GHWP

Strengthening Regulatory Framework

Facilitating Market Access

Promote Regulatory Convergence

Enhancing Public Health

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After joining GHWP:

Learning & Collaboration

- Learning from other GHWP members
- Sharing our expertise and experiences
- Collaborating on projects that drive regulatory harmonization and global convergence

Networking & Capacity Building

- Fostering relationships and build trust
- Engaged in working groups, training programs and workshops to promote capacity building.

Advocacy & Influence

- Advocate for policies and practices that align with our vision of an international harmonized medical regulatory framework, contributing to the GHWP's mission and objectives

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Thank you