Control of Medical Devices in Singapore

A Regulatory Update

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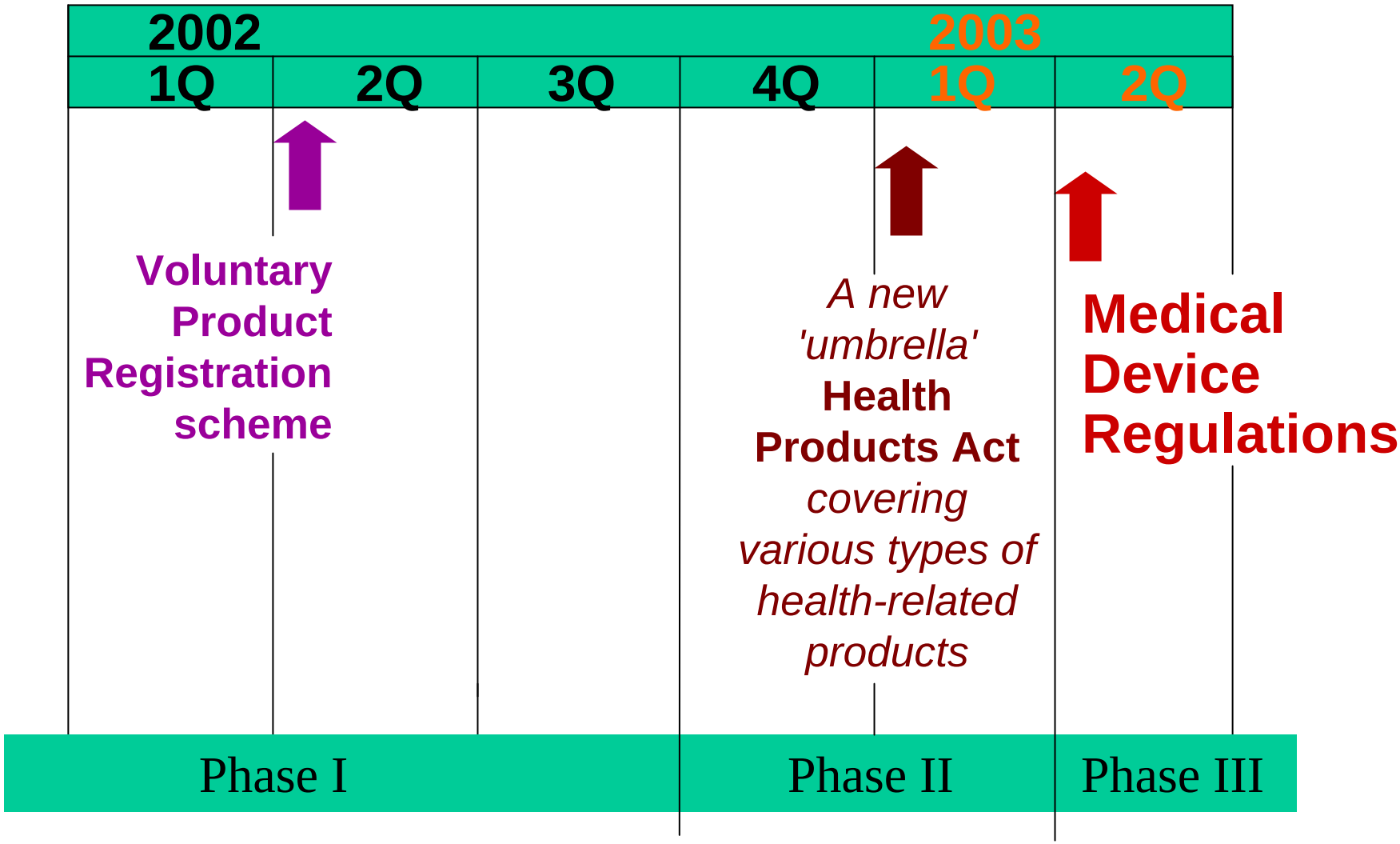
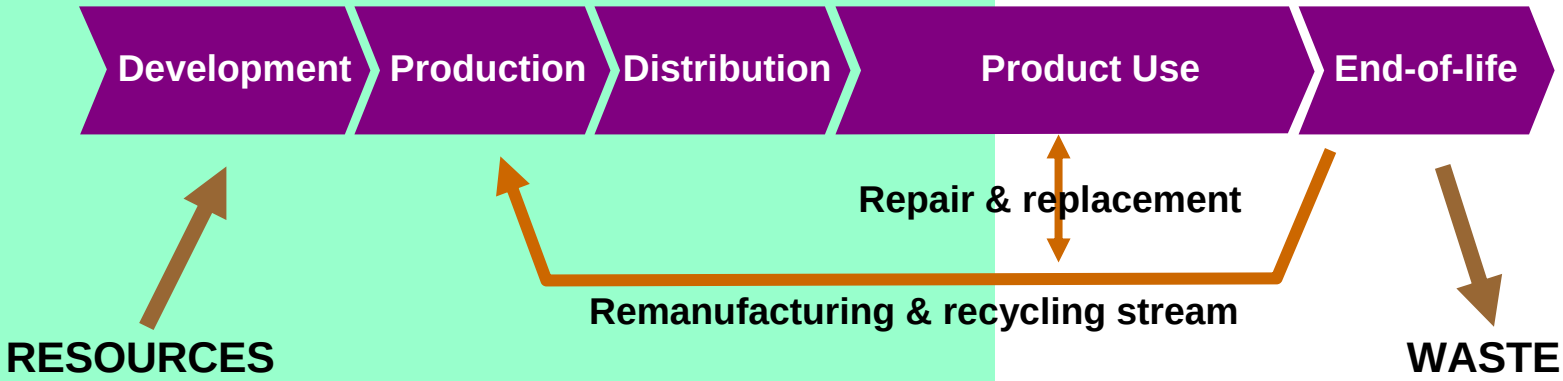
Implementation Timeline
for Regulatory framework



The life cycle of a manufactured product



SCOPE of Medical Device Regulatory framework

- Clinical trial
- Design/Manufacture & Quality Systems
- Conformity & Standards
- Labelling
- Device Marketing clearance
- Establishment licence
- Complaints
- Adverse incident reporting
- Recall

Harmonizing for the global market

Global Harmonisation Task Force

Mutual recognition agreements

ISO / IEC and others

HSA Certificates for Local Manufacturers

Local Manufacturers

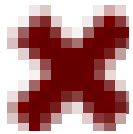
Level #1:

ISO 9000
ISO 13488
ISO 13485
QSR

Est Licence, Mfr

Quality System?
meeting medical device requirements

No



No certificate issuance

Yes

Level #2:

Product cleared for local marketing with HSA

Product Registration
Product Notification

Local Market?
meeting pre-market/notification requirements

No

Export Certificate (L#1)

Yes

Free Sale Certificate (L#1 & 2)

Establishment Licences:

"Manufacturer" means (a) a person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether the operations are carried out by that person himself or on his behalf by a third party; or (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name (apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual person).

"Local Authorised Representative" means a person established within Singapore who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in Singapore instead of the manufacturer.

Manufacturer's obligations

- Ensure that the medical device meets the essential principles and the conformity assessment procedures
- Keep objective evidence to establish that the medical device meets these requirements

REGULATORY ROADMAP

Establishment	Establishment Licensing	Product Licensing
MANUFACTURE Local	● **Manufacturer** ■ GMP/Design/Production	
IMPORT/SELL for placement on local market	● **Local Authorised Representative** ■ ● **Distributor** ■ Post-market requirements (Vigilance, Distribution records)	H ■ L
IMPORT/EXPORT <u>Not</u> for placement on local market	● **Importer/Exporter** Distribution records	A

■ Product Registration

◆ Product Notification

■ Listing on SMDR

LOW RISK

- Class I Medical devices & Other general IVDDs

Notification

Inform HSA about devices marketed

MEDIUM & HIGH RISK

- Class III, IIb, IIa Medical devices
  List A, List B and Self-testing IVDDs

Product Registration

Submit support documents for pre-market evaluation of safety, quality and performance

Singapore Medical Device Register

Product Listing

SINGAPORE MEDICAL DEVICE REGISTER (SMDR) is …

A register of legally available higher-risked medical devices and their wholesale supply and distribution

- On-line Product Registration portal

Manufacturer & Local Authorised Representative, Distributor

Product Approval

- Purchase from Product Listing (in SMDR)

Healthcare Institution & Public

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Product Registration Scheme

(1 April 2002)

- **MEDIUM & HIGH RISK**
  - **Class III, IIb, IIa Medical devices**
  - **List A, List B and Self-testing IVDDs**

- **Devices with prior regulatory approval/clearance from benchmark regulatory authorities**

Checklist of support documents

A:	**Regulatory Approval**
B:	Post-market Requirements
C:	Product Information
D:	Declaration of Conformity
E:	Status of Device Distribution
F:	Safety and Effectiveness Data
G:	Human Clinical Data

- US FDA Clearance/Approval
- EU Medical Device Directive
- Australia TGA Clearance/Approval
- Canada TPP Clearance/Approval
- Japan MHLW Clearance/Approval

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Established procedures for:

- *Distribution records*
- *Complaint handling*
- *Adverse incident reporting*
- *Recall*

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- **Device Description**
  Functions, Concepts, Materials, Design
- **Intended Use**
- **Instructions of Use**
- **Device Labelling**
  Instruction Manual
  Pack Labelling
  Promotional Material
  Product Brochure

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- **Safety and effectiveness requirements**
- **Product and Safety Standards**
- **Manufacturing process validation**
- **Quality systems**

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- Date of first introduction & use
- List of countries where it device is marketed
- Regulatory status in each country
- Reported problems and recalls in each country

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- **All studies to determine device safety and effectiveness**
  - *Physical, Chemical and Biological Testing - Pre-clinical*
  - *Investigational Testing on Human Subjects - Clinical*
  - *Process validation studies*
  - *Software validation studies*
  - *Literature studies*
- **Risk assessment – analysis, evaluation and reduction**

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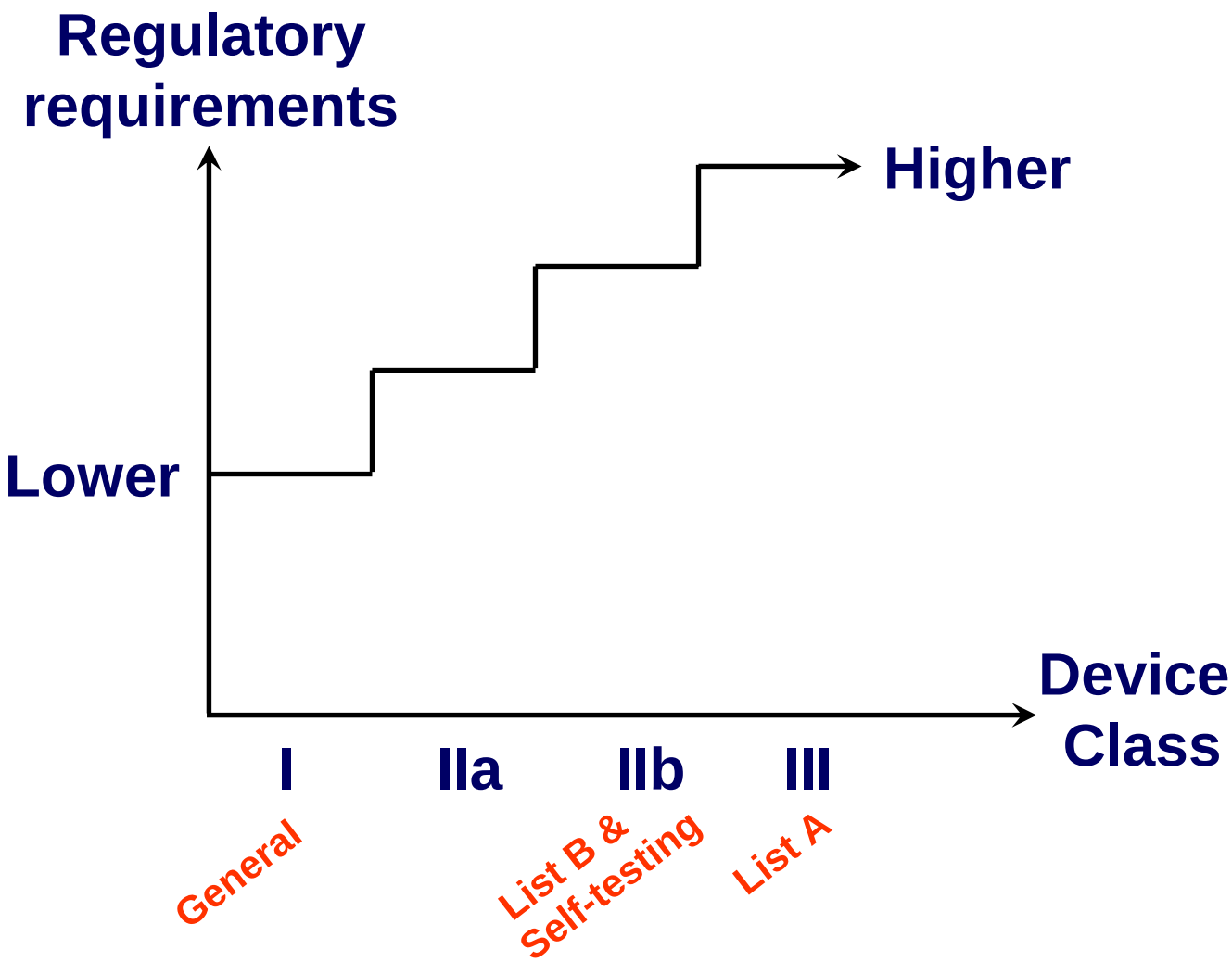
- **Specifically designed clinical investigations e.g. controlled clinical trials**
- **Peer-reviewed scientific literature**

Risk-based Regulatory Control



Risk-based Evaluation

Medical Devices:	I	IIa	IIb	III
A: Regulatory Approval				
B: Post-market Requirements				
C: Product Information	Claims			
D: Declaration of Conformity		Manufacture	Design & Manufacture	
E: Status of Device Distribution				
F: Safety and Effectiveness Data				
G: Human Clinical Data				

IVDDs:	General	List B / Self-testing	List A

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Product Registration Scheme

(1 April 2002)

A transitional phase to a regulated environment

- **A confidence building period**
- **A learning experience for stakeholders**
- **An opportunity to address issues that are obstacles to the path to market**

The Change

- *Minimum safety, quality & performance requirements for all devices*
- *Devices appropriately assessed according to the level of risk*
- *Globally aligned system eliminates unique local requirements*

Thank You.

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