Control of Medical Devices in Singapore

A Regulatory Update

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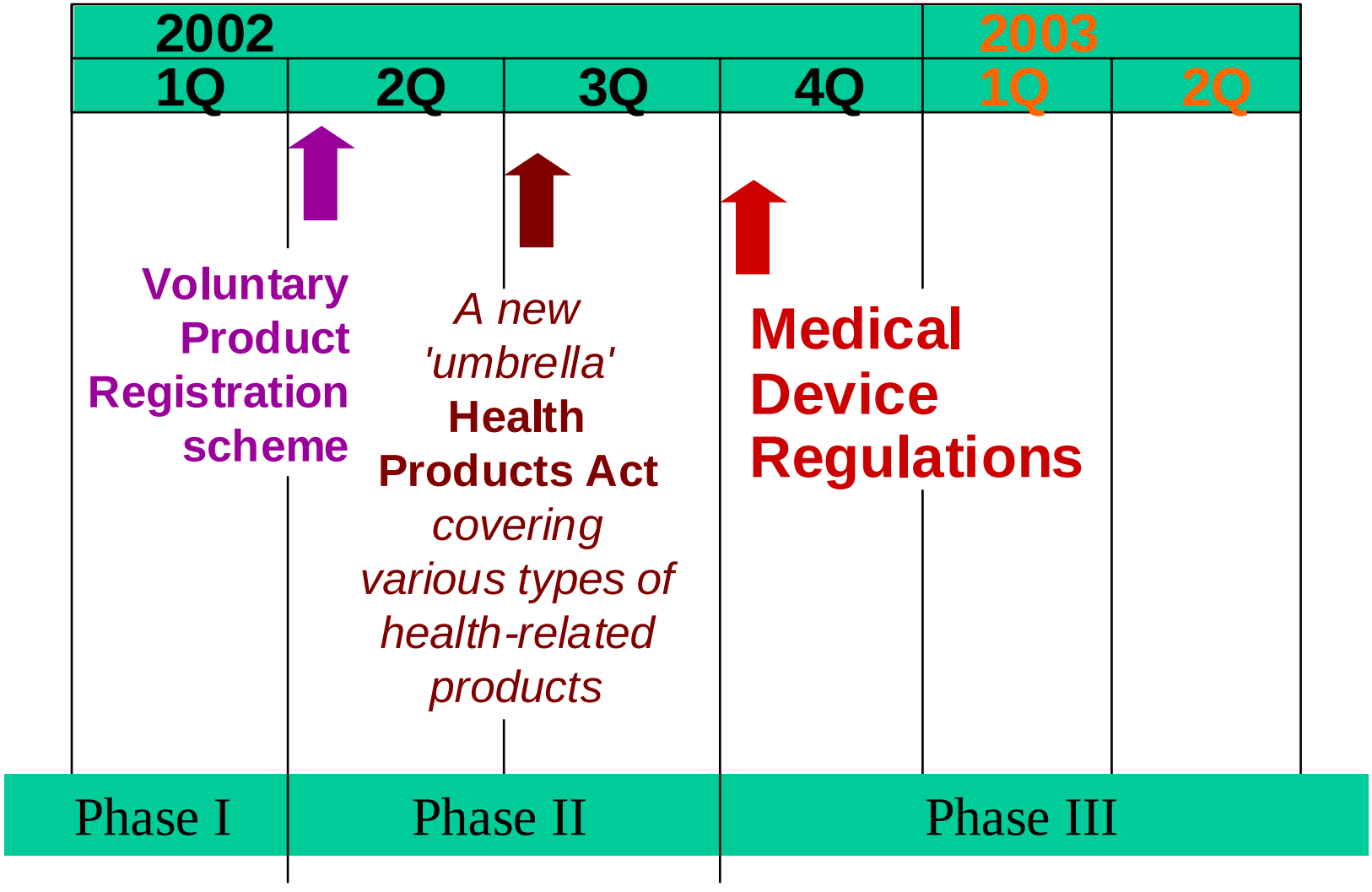
Implementation Timeline
for Regulatory framework



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

VOLUNTARY

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**

Guidance on Pre-market Submission Requirements

- **Information Leaflet #01/02:**

  Implementing Control of Medical Devices in Singapore

- **Information Leaflet #02/02:**

  Application to Place a Medical Device on the Singapore Market

- **Guidance Note #01/02:**

  Guidance on the Support Documents Required in the Application to Place a Medical Device on the Singapore Market

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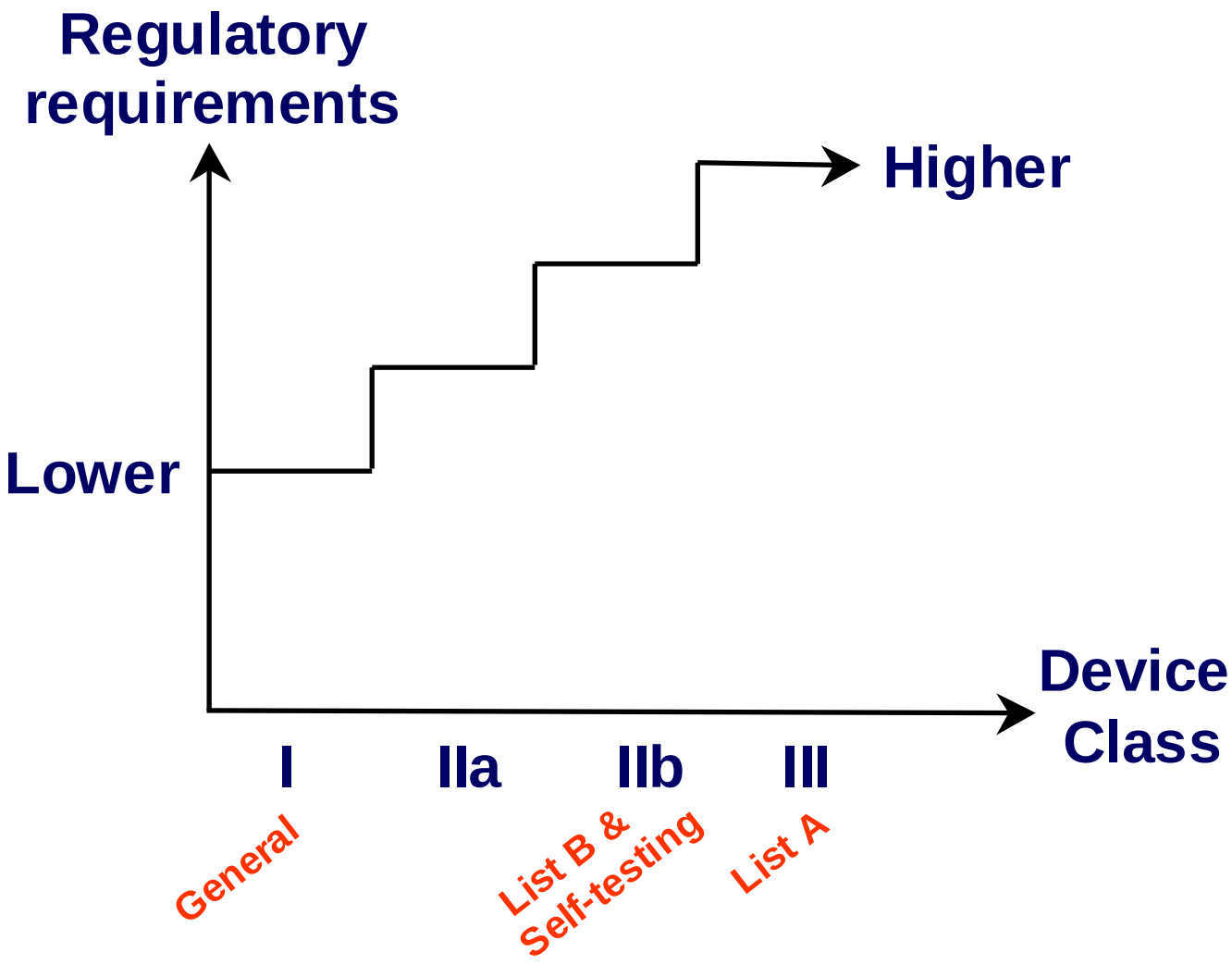
- **Specifically designed clinical investigations e.g. controlled clinical trials**
- **Peer-reviewed scientific literature**

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			Summary Results, Conclusion	Detailed Results Protocol Conclusion
G: Human Clinical Data				

IVDDs:	General	List B / Self-testing	List A

VOLUNTARY 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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