

Background of PAL Revision

- The Pharmaceutical Affairs Law (PAL) establishes regulations necessary for the manufacturing and distribution of Pharmaceutical products and medical devices to ensure their quality, safety and efficacy.
- The law is subject to successive reviews in response to international harmonization, progress of science and technology, corporate structural variations and other changes in socio-economic circumstances.

..Last revisions ..Medical Devices (1994) ..Pharmaceutical Products (1996)

Cabinet decided draft revision of PAL on April 5, 2002

Cabinet submitted to the Current Regular Parliament Session

PAL Revision: 3 Major Objectives

- Substantial Revision of Medical Devices Regulation
- Consolidation of Safety Measures for Biological Products
- Revision of Approval System and Enhancement of Post-marketing Safety Measures

Review of Classifications and Safety Measures Concerning Medical Devices j

International Classification	Current status and Proposed revision Classification of medical devices according to risk
Class A	Medical devices that are believed to pose extremely low risk to the human body even if they fail Examples: In vitro diagnostic devices, steel supplies, x-ray film, dental prosthetic supplies
Class B	Medical devices that are believed to pose low risk to the human body even if they fail Examples: MRI, electromanometers, electronic endoscopes, digestive catheters, ultrasonic diagnostic equipment, and dental alloys
Class C	Medical devices that are believed to pose medium risk to the human body if they fail Examples: dialyzers, artificial bones, respirators, and balloon catheters
Class D	Medical devices that are highly invasive upon the patient and may directly endanger the patient's life (high risk) if they fail Examples: pacemakers, artificial heart valves, and stents

EU system outline	FDA system outline
Notified Body's audit is not required	PMA or 510k is not required
Notified Body's audit is required	PMA or 510k is required
On-site inspection only	
Document review is required	

Current Pharmaceutical Affairs Law Regulations
Manufacturing regulations
Pre-wholesale, Pre-retail Notification is not required
Approval of manufacturing is not necessary
Pre-wholesale, Pre-retail notification is required
Minister's approval for manufacturing



Proposed Revision		
Classification name	Risk	Marketing regulations
General Medical Device	Extremely low	Pre-wholesale, Pre-retail Notification is not required Approval for marketing authorization is not required
Controlled Medical Device	Low	Pre-wholesale, Pre-retail notification is required* Introduction of third-party certification system
Specially Controlled Medical Device	Middle	Introduction of license system for wholesale or retail
	High	Minister's approval for marketing authorization

Note: The products shown as examples will be classified, in principle, based on GHTF recommendations. Minister of Health, Labour and Welfare to classify products according to recommendation of the Pharmaceutical Affairs and Food Sanitation Council. Although some medical devices are rented, and since rentals are handled in the same way as sales under the Pharmaceutical Affairs Law's regulations, they are omitted from this table.

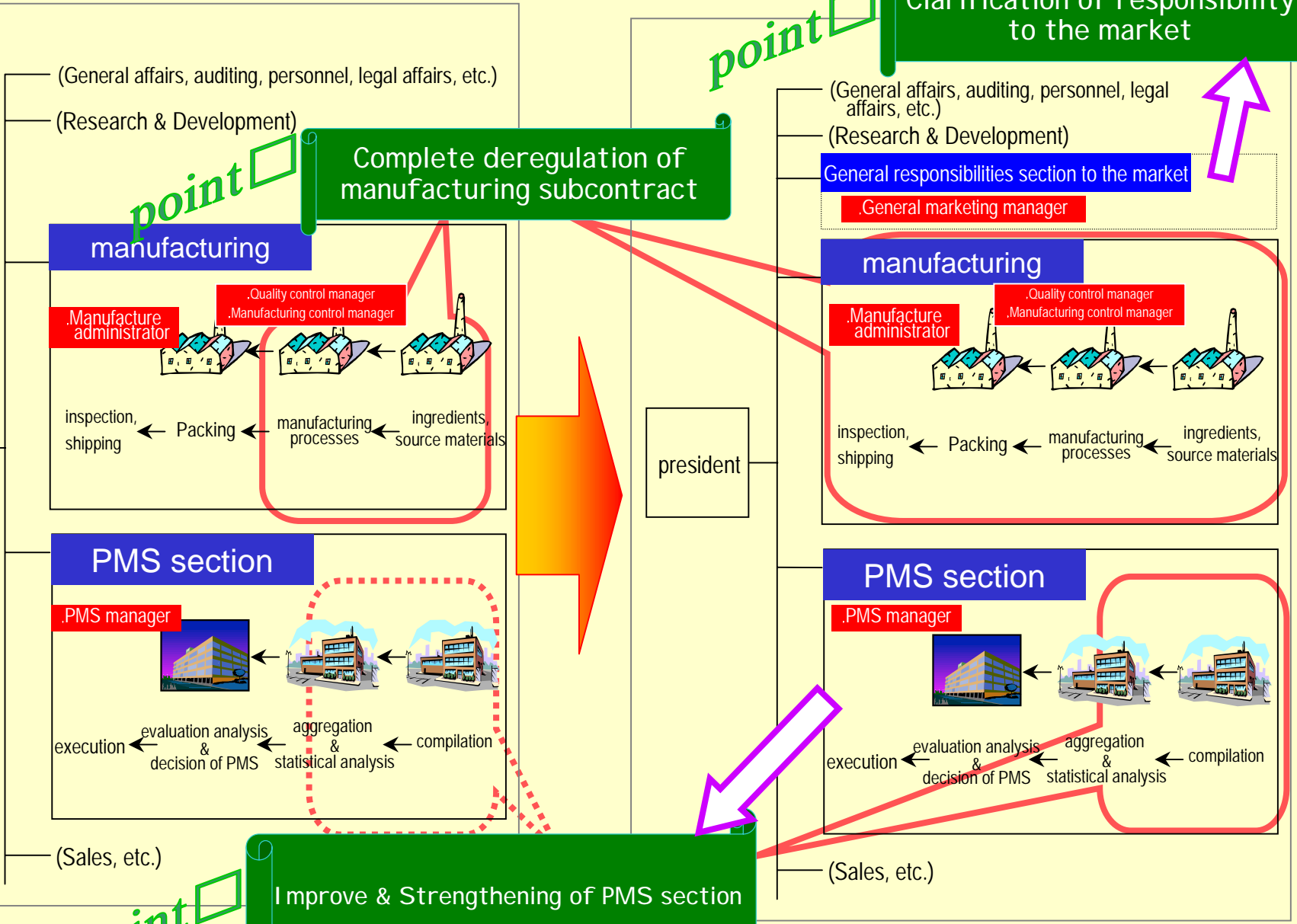
* Specially Designated Maintenance Required Medical Device, even those that are classified as low risk, require a license for distribution as do high-risk medical devices.

Changes in the Organizational Forms of Companies Acquiring Approval

point Clarification of responsibility to the market

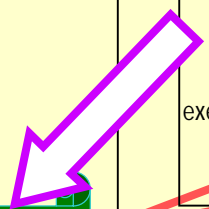
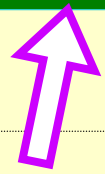
point Complete deregulation of manufacturing subcontract

point Improve & Strengthening of PMS section
Clarification of the range to subcontract



Legend

- Duties that can be subcontracted
- Especially important section that are conditions or observance matter for the license



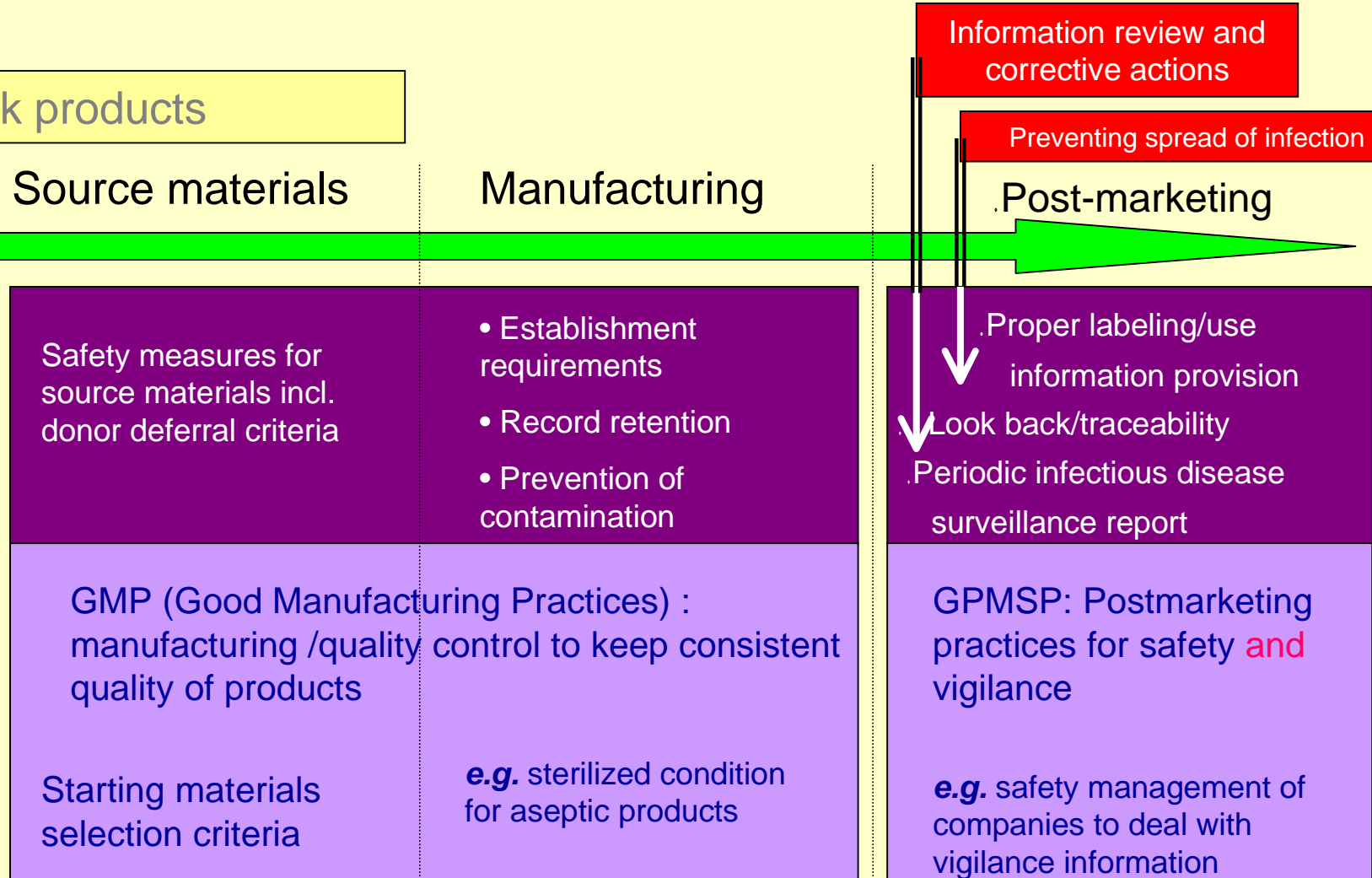
Consolidation of Safety Measures for Biological Products*

***Biological Products** : Products including ingredients derived from human or biological (excluding plants) source materials (such as cell, tissue, blood, etc.) , which should be subject to particular care from public health point of view

For higher risk products

“ADD-ON” for biological products

Chemical drug / normal devices



Information review and corrective actions

Preventing spread of infection

Post-marketing

Proper labeling/use information provision
Look back/traceability
Periodic infectious disease surveillance report

GPMSP: Postmarketing practices for safety and vigilance

e.g. safety management of companies to deal with vigilance information

Comparison Flowcharts of Approval and License (Current/Revised)

Points: (1) MAH's requirements for PMS system, (2) Allow complete subcontract manufacturing, (3) Introduce marketing approval system

Current

REVISED

Company A

