IMDRF International Medical Device Regulators Forum

“Revision of Pharmaceutical Affairs Law (PAL) ”

- Japan Update -

厚生労働省
Ministry of Health, Labour and Welfare

pmda

Revision of Pharmaceutical Affairs Law (PAL)

- Revision of Pharmaceutical Affairs Law (PAL) was adopted by the Diet, and announced on 27 November 2013.
- The amendment law will be enforced in November 2014.
- Ordinance and notification (detail of the new regulations) will be announced in advance to the new law enforcement.

Brief overview of revision of PAL

- Points of the amendment are to;
  1. Strengthen safety measures regarding drugs and medical devices
  2. Revise medical device regulations based on its characteristics
  3. Introduce Regenerative and Cellular Therapy Products (RCTP) & Gene Therapy Products (GTP) regulations based on their characteristics
- Name of PAL will be changed to

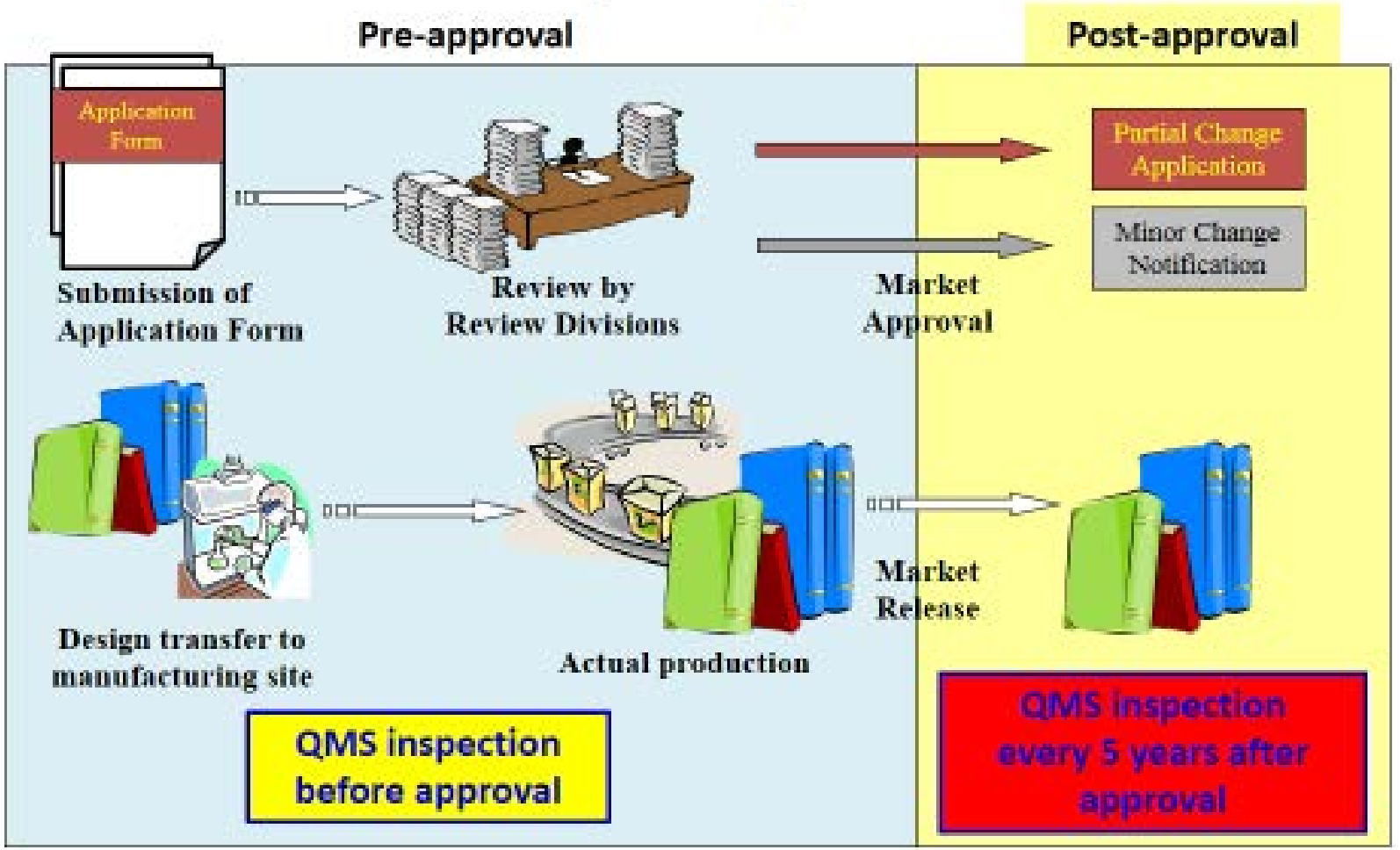
  "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics".
- The chapter for "Medical Device" will be prepared.

Scope of Third Party Certification will be expanded

GHTF Classification	
Class A	extremely low risk X-Ray film
Class B	low risk MRI, digestive catheters
Class C	medium risk artificial bones, dialyzer
Class D	high risk pacemaker, artificial heart valves

PAL classification		
Category	Pre-market regulation	Japanese MD Nomenclature
General MDs (Class I)	Self declaration	1,195
Controlled MDs (class II)	Third party Certification	1,799 (1,367 for 3rd Party)
Specially Controlled MDs (class III & IV)	Minister's Approval (Review by PMDA)	756
		342

Framework of Approval Review and QMS Inspection

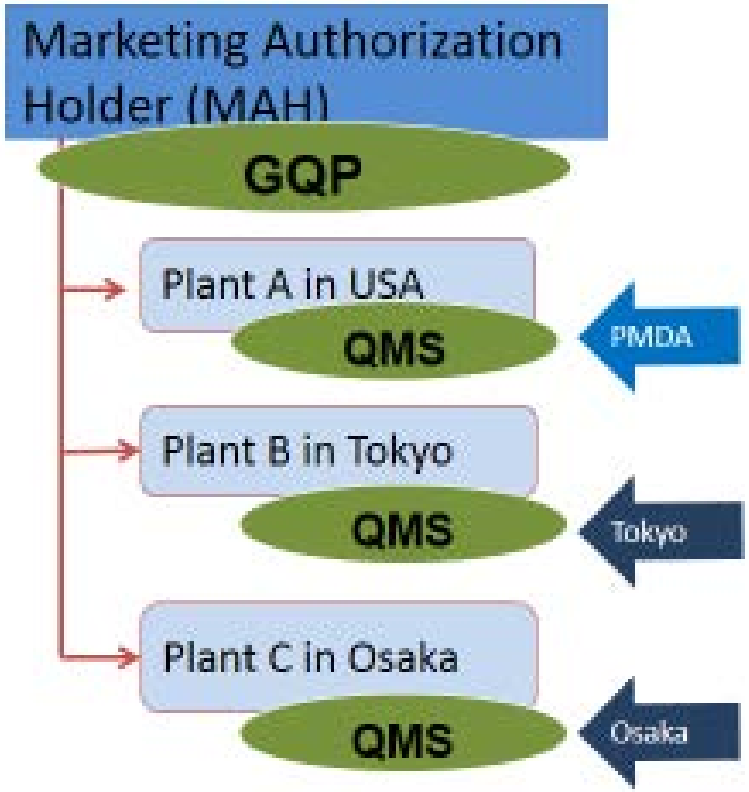


QMS regulation change under the revision of PAL

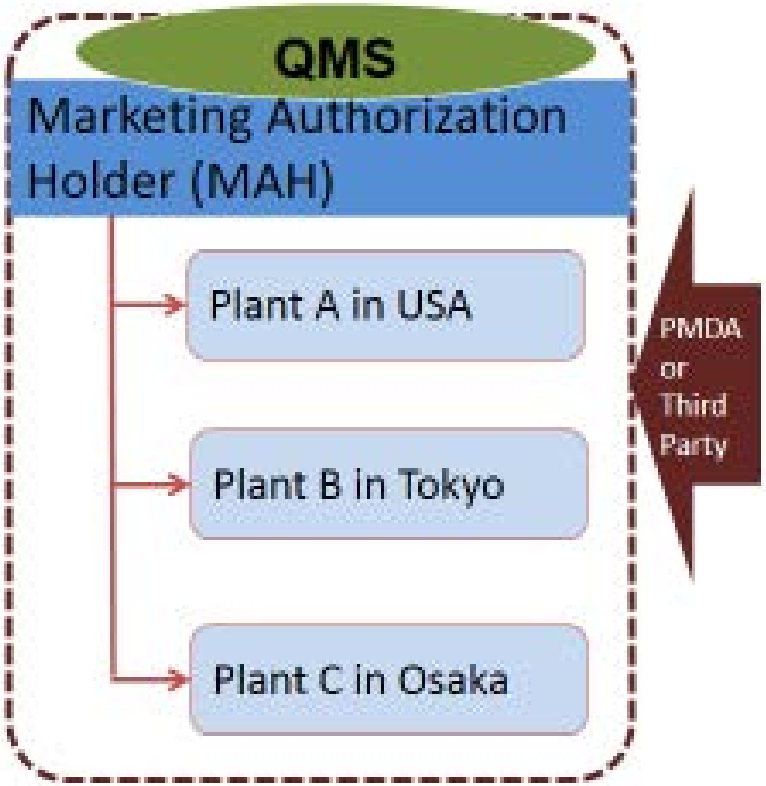
- QMS inspection applied to Market Authorization Holder(MAH)
- Foreign manufacturer's Accreditation to Registration
- QMS inspection per product family

QMS inspection will be applied to MAH, not each manufacturer

[Current QMS inspection]



[New QMS inspection]



Registration of Foreign Manufacturer

Foreign manufacturer need to register until the QMS inspection is conducted.

Accreditation of foreign manufacturer would change to Registration.

Accreditation → Registration

Manufacturing License would change to Registration.

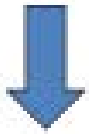
License for inland manufacturing → Registration

QMS inspection per product family

Ex) Product A, B ,C are Product family XXX

Now

QMS Inspection per Product A, B and C



After the revision of PAL

QMS Inspection per Product family XXX

※ QMS inspection per product family manufactured by the same establishments.

Standalone Medical Device Software (SMDS) will be regulated by the revised PAL

Current PAL

Image Diagnostic Apparatus

It processes, stores and displays image data from CT, MRI etc.

Hardware + Software (program)

Only combination of hardware and software is regulated.

Future

SMDS

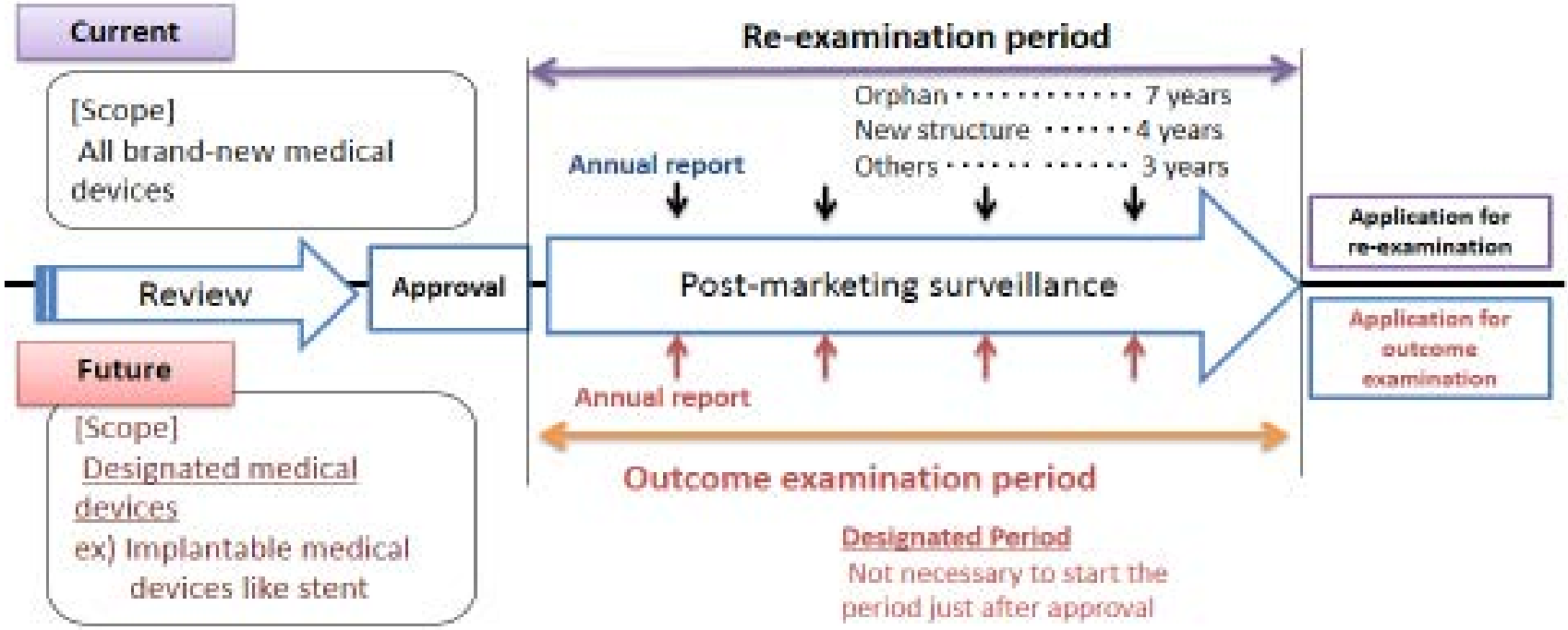
Software (program)

Standalone Software will also be regulated.

Outcome examination system, instead of re-examination system, will be introduced

Outcome examination system

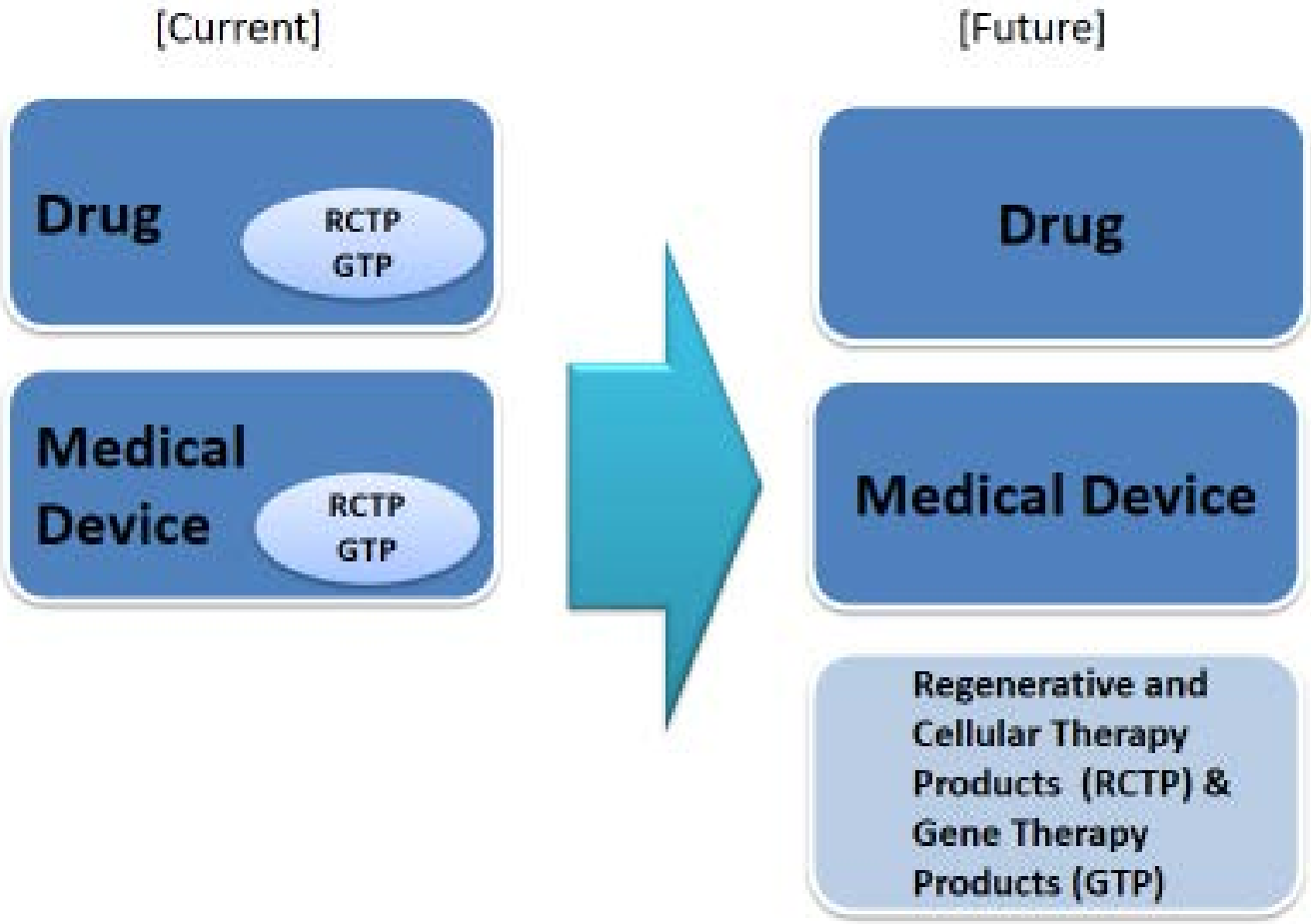
Outcomes (efficacy and safety) of a designated medical device under a post-marketing surveillance for an appropriate period will be examined.



Regulations on Package Insert will become more reasonable

1. Contents of package insert of class IV medical device should be notified to MHLW in advance.
2. Package insert notified will be uploaded on web-site.
3. Draft of package insert will be required as a material in a new medical device application.
4. Paper package insert of any medical devices can be omitted under certain conditions.

Regenerative and Cellular Therapy Products (RCTP), and Gene Therapy Products (GTP) will be newly categorized



Thank you

MHLW

PMDA