Changes in the Regulatory Environment Surrounding the Asian Region and Responses - Collaboration with PMDA -

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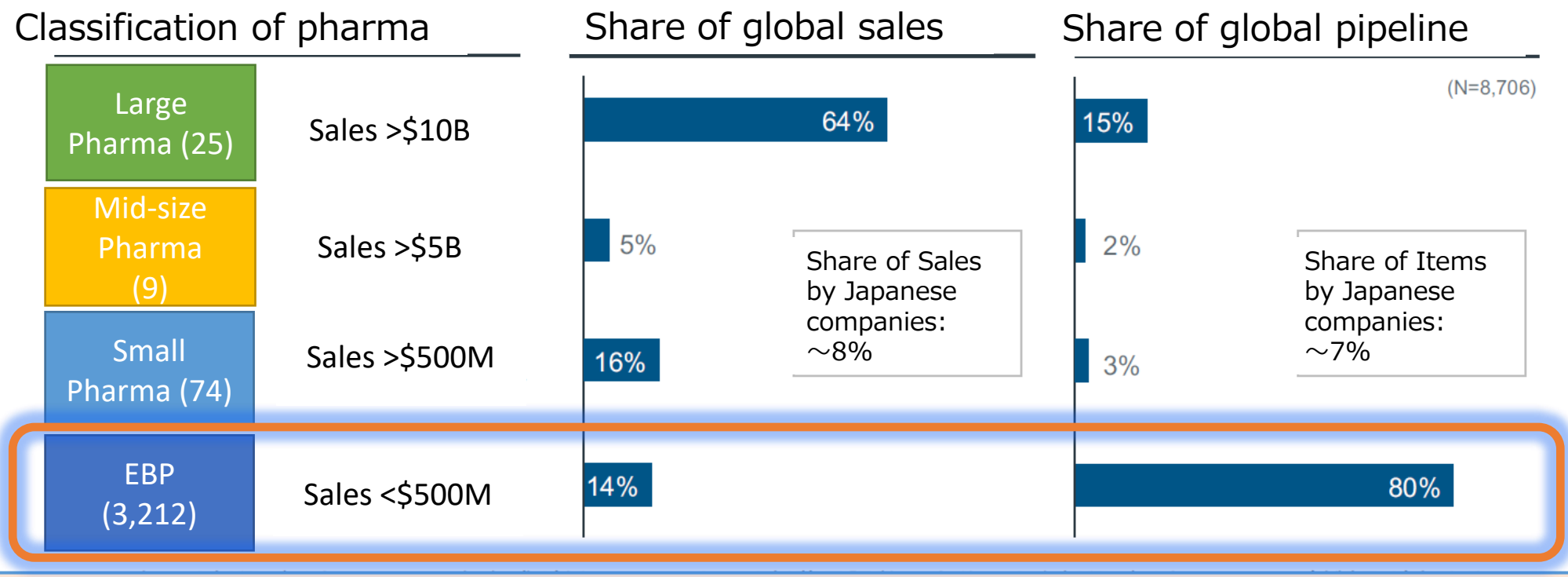
Change – Entities for drug development

MHLW
Pharm Industrial Vision
2021 Reference
13 Sep 2021

Emerging Biopharma's share of global sales and No. of products under development

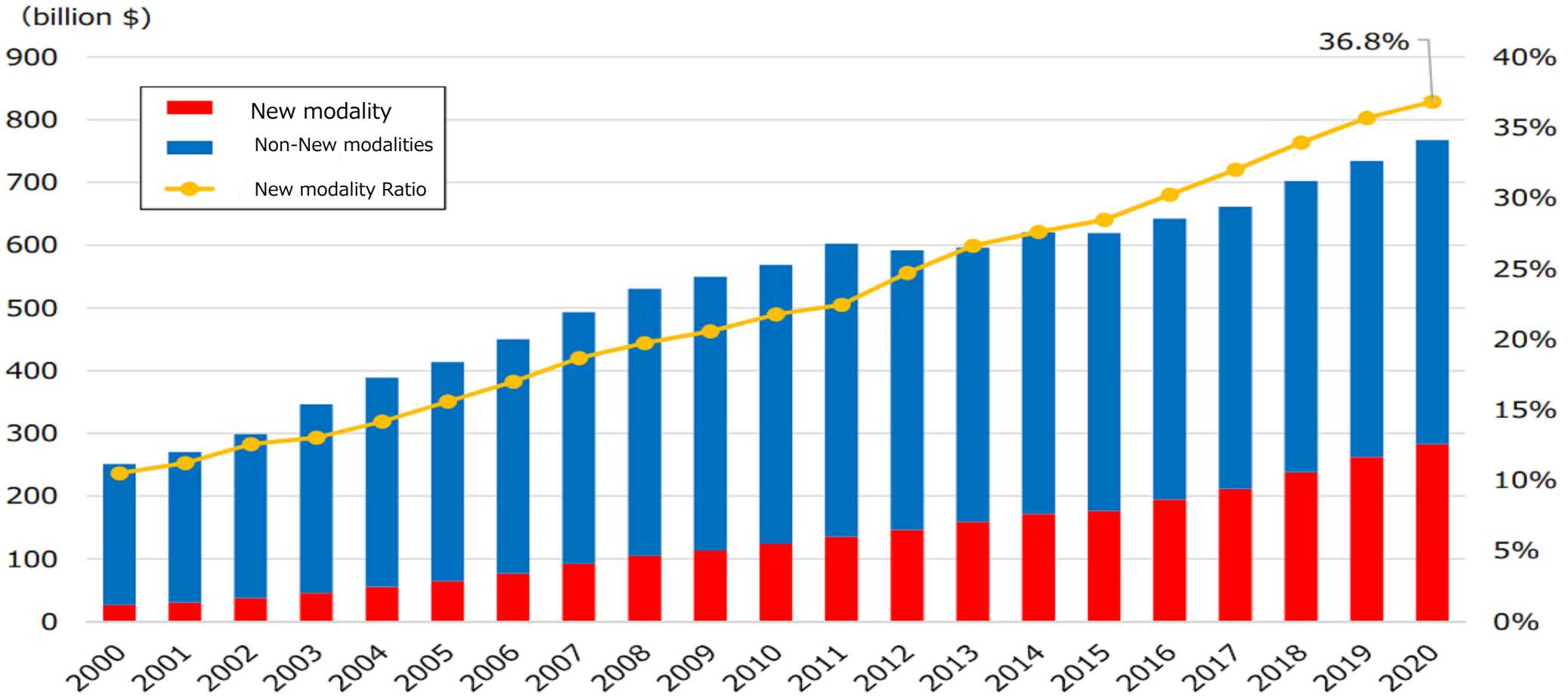


- Low presence of EBP in Japan
- Japanese companies have a 10% share in chemical products, but only 3% in new modalities.

IQVIA

Pmda Pharmaceuticals and Medical Devices Agency

Change – To New Modality
Trend of global pharmaceutical sales



* Novel modalities are items classified as "Biotechnology" in EvaluatePharma's "Technology" category. Antibodies, recombinant proteins, recombinant vaccines, nucleic acid drugs, gene-cell therapy, gene therapy, cell therapy, oncolytic virotherapy. https://www.mhlw.go.jp/content/10800000/000831974.pdf

COVID-19 Pandemic - Lessons learned

1) **Global Information Sharing :**
   Various forums for international discussion

Common nature

2) **Convergence of Regulatory Requirements:**
3) **Utilization of Remote inspection:**
4) **Promote Manufacturing Capacity:**

Need at ordinal status as well

5) **Combat Infodemic:** Statement for stakeholders (transparency)
6) **Regulatory Agility:** Agilities/Flexibilities implemented in each jurisdiction

Pandemic oriented

Pharmaceuticals and Medical Devices Agency

Common issues - Asian Regulators

1. Start-up companies: *how do we access them?*
2. New modality products:
   how do we coordinate the environment for clinical study?
3. Further convergence of Regulatory requirements
   - Utilize technical tools (data standard; remote inspection)

1. To strengthen Information sharing
2. To progress regulatory cooperation
3. To enhance regulatory capacity building
4. To accelerate clinical trial site network

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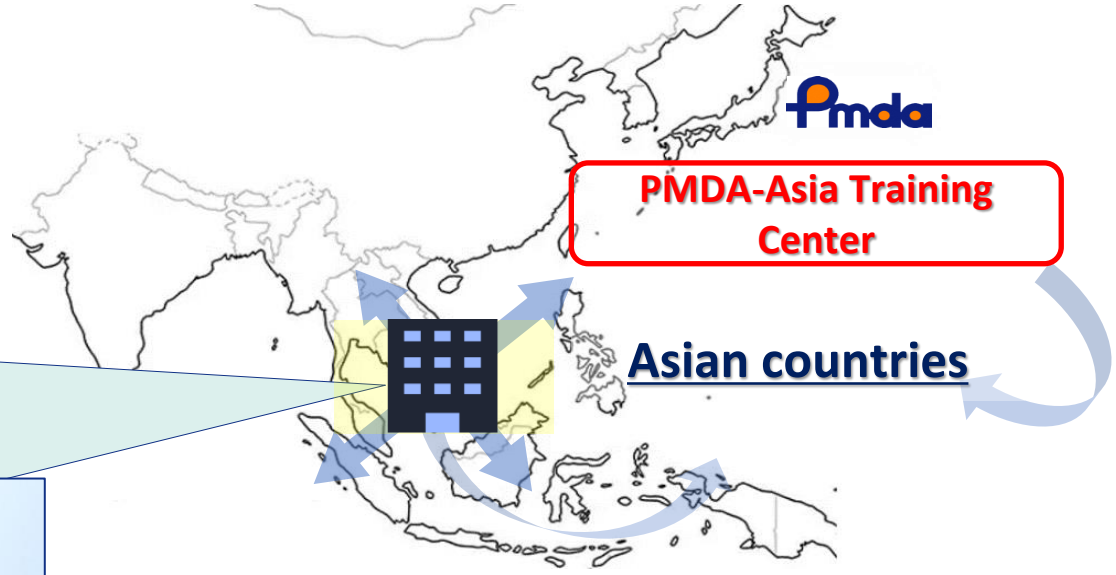
What can PMDA do?

1. To strengthen Information sharing
2. To progress regulatory cooperation
3. To enhance regulatory capacity building
4. To accelerate clinical trial site network

PMDA Asia Office can facilitate

- **Training for specific needs**
- **Common regulatory cooperation thru bilateral communication**
- **Collaboration for reliance (bilateral/ASEAN Joint Assessment)**
- **Cooperation on Clinical Trial network from regulatory perspective**

Pharmaceuticals and Medical Devices Development Ecosystem in Asia



- Establishment of regulatory basis with Asian regulatory authorities
- Exchange of information with industries that enters in Asian regions and Identification of issues
- Collaboration with related Stakeholders

- Establish parallel and circulating support system
- Improve clinical development environment / strengthen regulatory capacity

→ Establish Pharmaceuticals and Medical Devices Development Ecosystem in Asia

Thank you very much!!

Please visit the PMDA website

https://www.pmda.go.jp/english/index.html