



# A Restored Biopharmaceutical Innovation Ecosystem Will Benefit Japan's Health and Economy

Proposal for a National Strategy and Public-Private Council

July 30, 2024

Pharmaceutical Research and Manufacturers of America

# Japan's Drug Loss Will Worsen Without Needed Policy Reforms

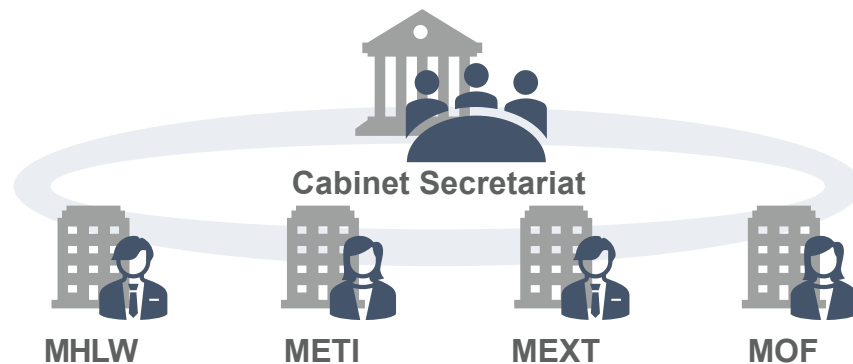
Over two-thirds of new medicines in late-stage clinical development in the United States or Europe have not yet begun development in Japan

Current Drug Loss	Future Drug Loss																																																	
<div><div>!</div><div>225 new medicines launched in the U.S. or Europe but not Japan between 2012 and the end of 2021</div></div> <div><div>108 (48%) of 225 launched medicines have not begun development in Japan</div><div><table><tr><th>Highest Level of Development in Japan</th><th>Percentage</th></tr><tr><td>No Development</td><td>48%</td></tr><tr><td>Preclinical</td><td>2%</td></tr><tr><td>Phase 1 Clinical Trial</td><td>6%</td></tr><tr><td>Phase 2 Clinical Trial</td><td>5%</td></tr><tr><td>Phase 3 Clinical Trial</td><td>20%</td></tr><tr><td>Pre-registration</td><td>15%</td></tr><tr><td>Registered</td><td>5%</td></tr><tr><td>Other</td><td>5%</td></tr></table></div></div>	Highest Level of Development in Japan	Percentage	No Development	48%	Preclinical	2%	Phase 1 Clinical Trial	6%	Phase 2 Clinical Trial	5%	Phase 3 Clinical Trial	20%	Pre-registration	15%	Registered	5%	Other	5%	<div><div>!</div><div>589 new medicines are currently in Phase 3 clinical trials in the U.S. or Europe</div></div> <div><div>404 (69%) of 589 future new medicines have not begun development in Japan</div><div><table><tr><th>Highest Level of Development in Japan</th><th>Percentage</th></tr><tr><td>No Development</td><td>69%</td></tr><tr><td>Preclinical</td><td>3%</td></tr><tr><td>Phase 1 Clinical Trial</td><td>3%</td></tr><tr><td>Phase 2 Clinical Trial</td><td>4%</td></tr><tr><td>Phase 3 Clinical Trial</td><td>22%</td></tr></table></div></div>	Highest Level of Development in Japan	Percentage	No Development	69%	Preclinical	3%	Phase 1 Clinical Trial	3%	Phase 2 Clinical Trial	4%	Phase 3 Clinical Trial	22%	<div><div>!</div><div>404 new medicines not in development in Japan target major areas of unmet medical need</div></div> <div><div>Therapy areas of 404 future new medicines not in development in Japan</div><div><table><tr><th>Therapy Area</th><th>Percentage</th></tr><tr><td>Infectious Disease</td><td>23%</td></tr><tr><td>Oncology</td><td>22%</td></tr><tr><td>Central Nervous System</td><td>19%</td></tr><tr><td>Autoimmune and Inflammation</td><td>15%</td></tr><tr><td>Endocrinology and Metabolism</td><td>14%</td></tr><tr><td>Other</td><td>12%</td></tr><tr><td>Cardiovascular</td><td>8%</td></tr><tr><td>Ophthalmology</td><td>6%</td></tr></table></div></div>	Therapy Area	Percentage	Infectious Disease	23%	Oncology	22%	Central Nervous System	19%	Autoimmune and Inflammation	15%	Endocrinology and Metabolism	14%	Other	12%	Cardiovascular	8%	Ophthalmology	6%
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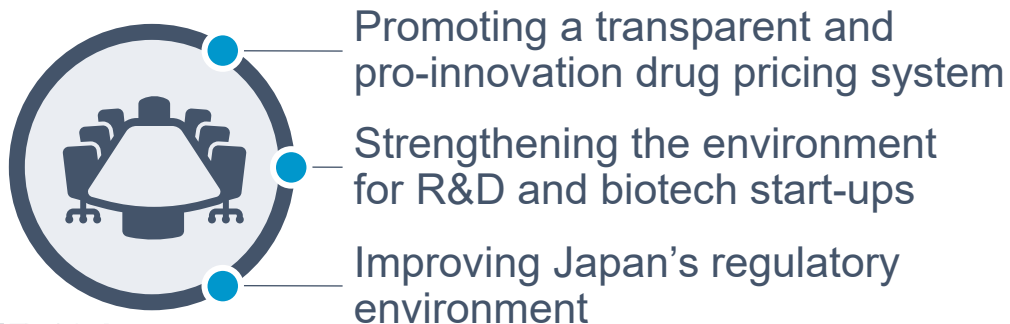
# Japan Needs a Bold New National Biopharmaceutical Strategy

**A permanent cross-ministerial structure should develop the strategy with regular and substantive input from the global biopharmaceutical industry**

## Permanent Cross-Ministerial Body



## Public-Private Council Focus



## Required Actions



Direct relevant ministries to formulate national strategy with goals, policies and KPIs



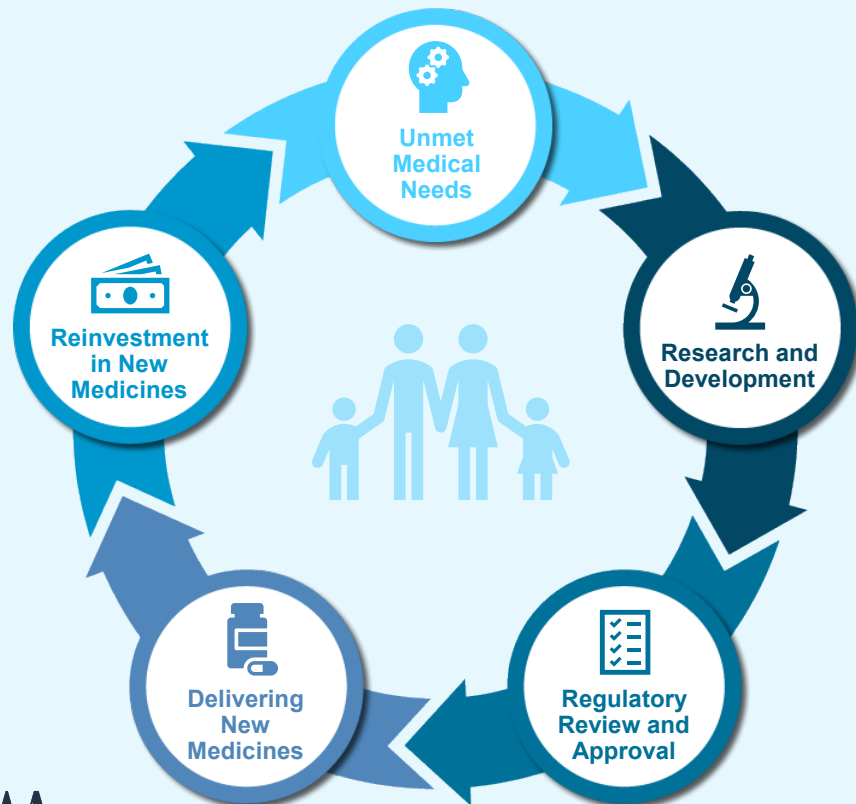
Actively monitor KPIs and take measures to ensure progress on goals



Establish channels for regular input from multinational biopharmaceutical companies

# A Restored Biopharmaceutical Innovation Ecosystem Will Bring Significant Benefits to Japan

## Biopharmaceutical Innovation Ecosystem



## Benefits to Japan



Drug discovery and faster patient access to the latest medicines



A more effective and sustainable health care system



Increased investment, jobs and economic growth

