

官民協議会

医薬品産業の成長に向けて

一国民の健康を守るための国家戦略一

2025年6月26日 日本製薬工業協会 会長 宮柱 明日香

官民協議会に求めること



日本の成長を担う基幹産業である医薬品産業を、国民の健康と経済の両面に資する重要な国家 戦略として位置づけ、国内産業としての更なる活力強化および国際的な展開の促進に向けて、長期的な戦略プランの策定を目指すにあたり、以下2点を中心に議論を継続頂きたい

1. 革新的新薬の研究開発・製造への継続的な投資

- □ 投資対象・期間について産官学横断的に十分な議論を踏まえて決定し、決定した投資方針は責任をもって 長期的にフォローし、安定的な支援を継続する
- 省庁横断的な、統合的かつ実効性のある政策対応を推進する

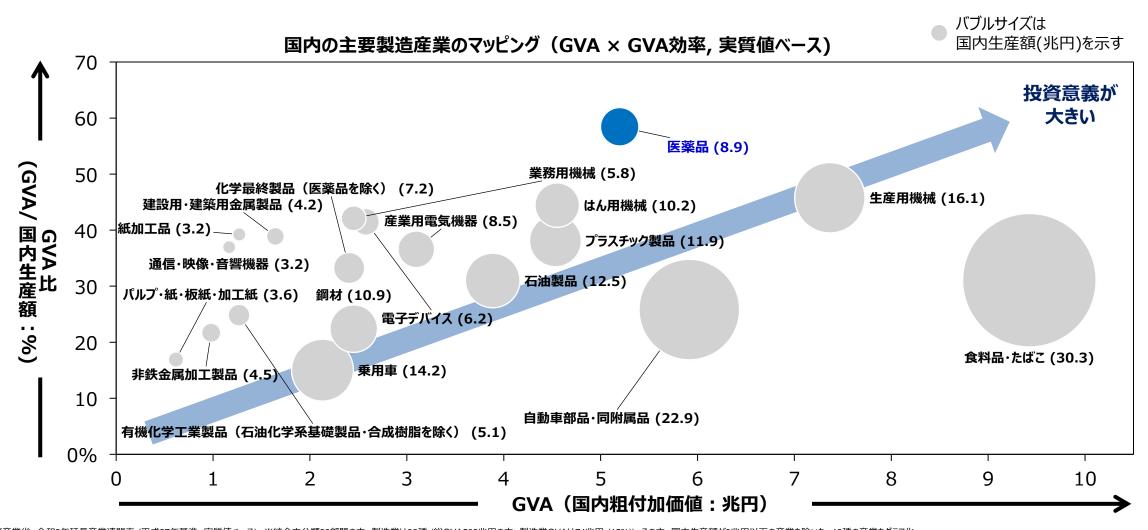
2. 社会保障財政、薬価制度設計に関する議論

- □ 「社会保障費の経済・物価動向等を踏まえた予算の対応」の具体化に向けて、薬価への反映方法について 議論を進める
- イノベーションを適切に評価し予見性を高める新たな薬価制度のあり方について、具体的な検討を進める

医薬品産業は日本の成長を担う基幹産業



医薬品は国内生産額に占めるGVA(粗付加価値)額が高く、投資意義が大きい



医薬品産業への国主導の戦略的投資・政策を求める





医薬品産業は、国家安全保障の観点からも重要な成長産業であり、今、重要な局面を迎えている

圃

産業の潮流変化

<u>\$</u>_

開発・製造体制の構造転換



グローバル競争の激化

医薬品

- 低分子から高分子、バイオ、遺伝子 治療薬など、新規モダリティ等の革新 的医薬品へ移行
- 革新的医薬品の実用化から市場導入までに必要な人材、科学的知見・ 技術、評価基準、及び規制等の整備 が不足

- 医薬品産業は公衆衛生の基盤だが 輸入依存が高く、経済安全保障リス クやサプライチェーン断絶により、有事 には製造・安定供給が脅かされる 懸念
- 水平分業型へ移行が進んでいるが、アカデミア、スタートアップ、CDMOなどとのパートナーシップが十分な成果に繋がらない

- 研究開発には長期かつ多額の投資が 必要であり、製品のグローバル展開が 不可欠
- ・ 予見性に欠ける薬価制度により日本 市場への開発・投資が減少
- その結果、日本の製薬企業は国際的 プレゼンス低下(創薬力、世界シェア)

新技術に対応するための投資

国民の健康を守る国内基盤の強化

日本市場の魅力を向上させる政策

半導体

技術革新への対応の遅れ

自社完結型構造から脱却できず

日本企業の競争力低下

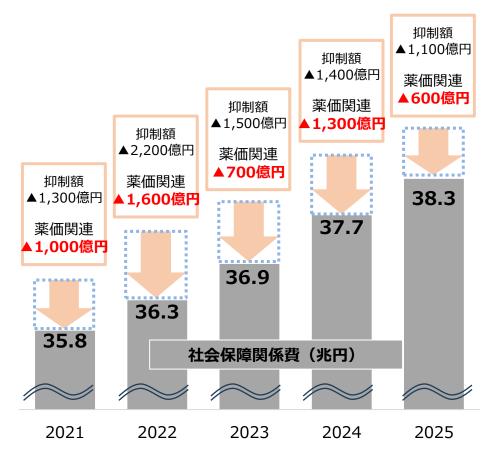
日本の医薬品産業への投資・開発を呼び込むために



「予見性のある薬価制度」の構築により国内医薬品市場の成長を促進

社会保障関係費の削減額

社会保障削減額のうち70%以上が薬価によるもの1



取り組むべき課題

①社会保障関係費の枠組み拡大

- 国内医薬品市場の2015~2024年で成長率は僅か0.4%²
- □ 高齢化による増加分に相当する伸びにこうした経済・物価 動向等を踏まえた対応に相当する増加分を加算する

(「骨太の方針2025」より引用)

②予見性の高い薬価制度改革

ロ 革新的新薬の適切な価値評価

- 新規モダリティ等の革新性を評価できる新たな仕組み検討
- 柔軟な類似薬の選定

ロ 革新的新薬の特許期間中の薬価維持

- カテゴリー別の薬価改定
- 市場拡大再算定の廃止
- 費用対効果評価の抜本的なあり方検討

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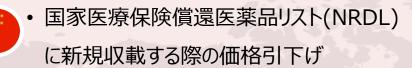
日本の医薬品産業の競争力向上に今こそ取り組むべき



各国で医薬品市場環境の厳しさが増す中、日本には投資を呼び込める機会がある



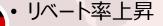
- 医薬品市場の成長上限率の設定
- 薬剤費上限超過時に製薬企業が払い戻し





- IRA法に基づき薬価引き下げ
- 米国新政権

(相互関税・最恵国待遇価格)



・ 自由薬価期間短縮(12ヶ月→6ヶ月)

- 疾患重症度別の償還率
- 予算上限を超えた薬剤費は企業が返金

- ・予見性の低い薬価政策決定プロセス
- ・社会保障費の財源を薬剤費から捻出
- ・ 承認後原則60日以内の薬価収載
- ・皆保険により収載後の薬剤アクセスが容易





Public-Private Council

Japan's Pharmaceutical Growth Strategy

-A National Imperative for Health Security-

June 26, 2025
Asuka Miyabashira
President, Japan Pharmaceutical Manufacturers Association

What We Ask of the Public-Private Council



In positioning the pharmaceutical industry—one of Japan's key growth sectors—as a vital component of national strategy that contributes to both public health and economic prosperity, we respectfully request that the Council continue discussions with a focus on the following two key areas, with the aim of formulating a long-term strategic plan to further invigorate the domestic industry and promote its global expansion:

1. Sustained investment in R&D and manufacturing of innovative new drugs

- Investment targets and timeframes should be determined through cross-sectoral discussions among government, industry, and academia. Once established, the investment policy must be followed through with long-term commitment and stable support.
- A coordinated, cross-ministerial approach is essential to ensure integrated and effective policy implementation.

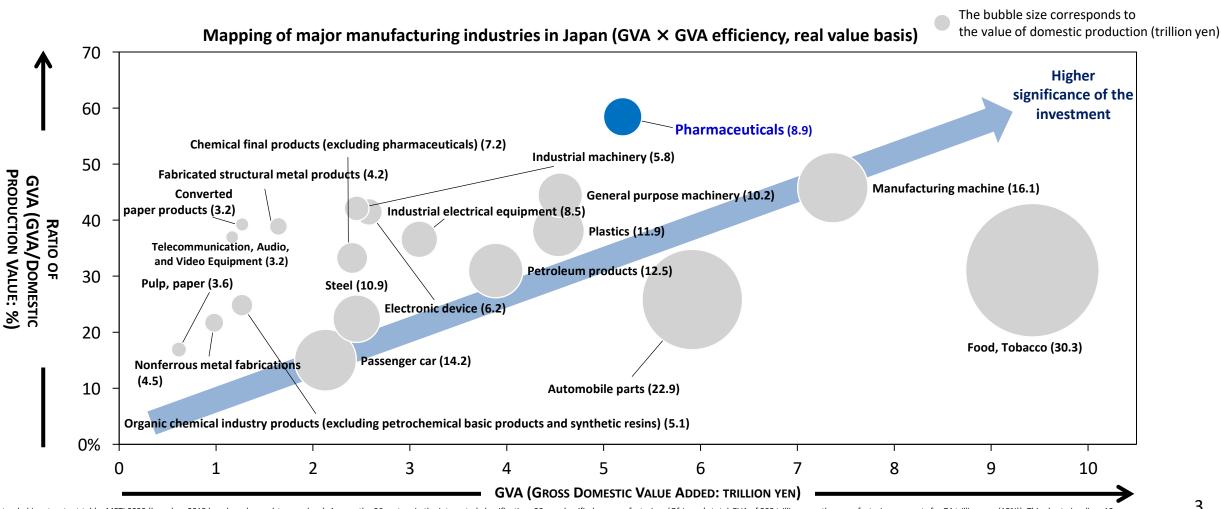
2. Discussions on Social Security Financing and Drug Pricing System Design

- In order to materialize the concept of "budgeting that reflects economic and price trends in social security expenditures," we urge continued dialogue on how such considerations should be reflected in drug pricing.
- We also call for concrete deliberation on a new drug pricing system that appropriately values innovation and enhances predictability.

The pharmaceutical industry plays a key role in Japan's growth



Pharmaceuticals have a high GVA in domestic production, underscoring its importance as an investment target



Strategic Investment in Pharma:

A Government-Led Approach Inspired by Semiconductors



Central to public health and national resilience, the pharmaceutical sector now demands bold, strategic action



Shifting technology landscape



Structural change in development/manufacturing



Intensifying global competition



- Japan's pharmaceutical sector is shifting from small molecules to advanced modalities such as biologics and gene therapies.
- Key enablers -talent, science, standards, and regulationremain underdeveloped for the successful market entry of innovative therapies

Investing in innovation

- While the pharmaceutical industry serves as the foundation of public health, Japan remains highly dependent on imports, posing significant risks to economic security and supply chain resilience, especially in times of crisis
- Despite a shift toward horizontal specialization, partnerships among academia, startups, and CDMOs have yet to yield sufficient results

Strengthening domestic infrastructure for public health

- **Long-term and substantial R&D investment is essential.** Global product expansion is critical.
- Unpredictable drug pricing system discourages development and investment in the Japanese market
- As a result, Japanese
 pharmaceutical companies are
 losing international presence in
 innovation and global market share.

Enhancing Japan's market attractiveness through policy

- Semiconductors
- Lagging adaptation to technological change

Slow transition from vertically integrated models

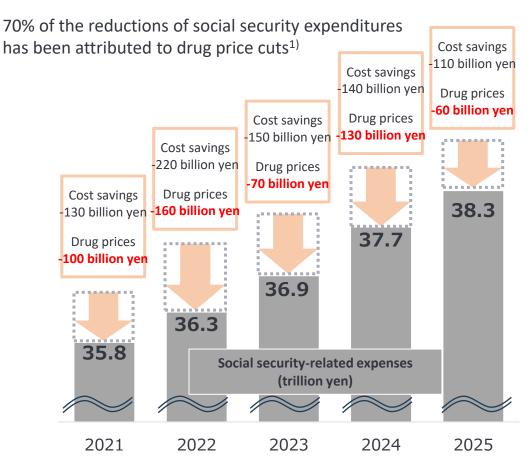
Declining global competitiveness of Japanese companies

Attracting Investment and Innovation to Japan's Pharma Sector



Establishing a drug pricing system with long-term predictability to accelerate the market growth

Social security cost savings



Policy Priorities

1. Expand the framework for social security expenditures

- ☐ The growth rate of Japan market from 2015 to 2024 was **only 0.4**%²⁾
- ☐ In addition to the natural increase associated with population aging, an additional adjustment should be made to reflect economic and price trends.

(Honebuto policy 2025)

2. Reform the drug pricing system with predictability

- Appropriate value assessment of innovative drugs
 - New framework to evaluate innovation in emerging modalities
 - Flexible selection of comparator drugs
- Price maintenance during patent period for innovative drugs
 - Category-based drug price revisions
 - Abolition of market expansion repricing
 - Fundamental review of cost-effectiveness evaluation

Now Is the Time to Strengthen Japan's Pharmaceutical Competitiveness



While global pharma market environment gets tougher, Japan has an opportunity to attract investment



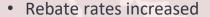
- A growth cap set for the pharmaceutical market
- Pharmaceutical companies reimburse when drug costs exceed agreed thresholds



Newly listed drugs on the National Reimbursement Drug List (NRDL) are subject to price reductions



- Drug price reductions under IRA Act
- New U.S. Administration (reciprocal tariffs, Most-Favored-Nation pricing)



 The free drug price period for new drugs shortened from 12 months to 6 months

- Reimbursement rates difined by disease severity
- Drug costs exceeding budget ceiling are subject to reimbursement by pharmaceutical companies

- Low predictability of the drug pricing policy
- Offset social security expenses by cutting drug prices
- Drug price listing within 60 days after approval
- Access to medicine secured by Universal Health Coverage

