HPR46

COMPARATIVE ANALYSIS OF ACCESS AND PRICING TIMELINES FOR INNOVATIVE MEDICINES IN THE US, EUROPE, AND JAPAN (PRE- AND POST-PRICING REFORM), 2021–2025

Haney E, Lee MK, Bailey R, Cesari E
Inbeeo, London, United Kingdom

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BACKGROUND

Over the past decade, Japan's pharmaceutical landscape has experienced a series of disruptive policy changes, including annual repricing of patented drugs [1,2,3].

These policy shifts have intensified Japan's drug lag, leading to delayed access, product withdrawals, and fewer launches—while many innovative therapies reach the U.S. and European markets years earlier[4]. To address this, Japan's Chuikyo introduced a pricing reform in April 2024 to accelerate access to National Health Insurance–listed medicines[5].

This research assessed the impact of the reform by comparing regulatory and reimbursement timelines and list prices in Japan versus the US and key markets (France, Germany, and the UK) pre- and post-reform.

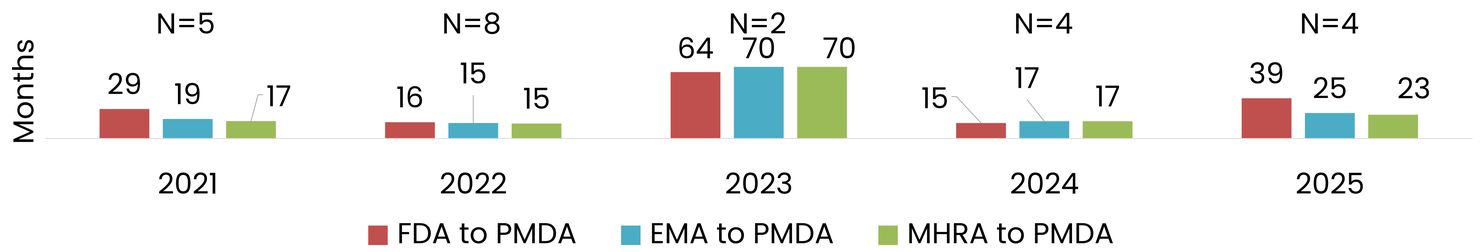
METHODOLOGY

Access and pricing trends were analysed using descriptive statistics to compare mean regulatory approval and public coverage timelines, launch prices and 1-year post launch price change for all covered branded innovative drugs in Japan, Germany, France, the UK, and the US.

Innovative drugs, defined as those granted an innovativeness /usefulness premium by Japan's Ministry of Health, Labour and Welfare (MHLW) between January 2021 and May 2025 were stratified into pre-reform (January 2021–April 2024) and post-reform (May 2024–May 2025) cohorts6. Data were extracted from publicly available regulatory (Pharmaceuticals and Medical Devices Agency (PMDA), US Food and Drug Administration (FDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), Health Technology Assessment, and pricing databases[1,7,8,9] .

RESULTS

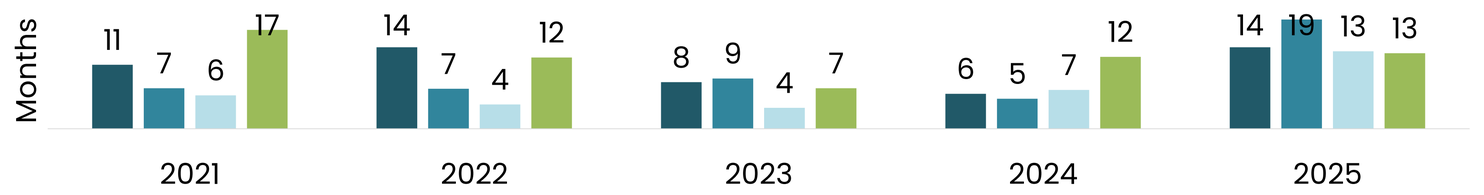
FIGURE 1. MEAN TIME INTERVALS (MONTHS) FROM FDA, EMA, AND MHRA APPROVALS TO PMDA APPROVAL, 2021–2025



	Pre-reform (2021-23)	Post-reform (2024-25)
FDA → PMDA	36	27
EMA → PMDA	35	21
MHRA → PMDA	34	20

The analysis of 23 innovative drugs showed that pre-reform, the mean PMDA approval lag versus the FDA, EMA, and MHRA averaged 36, 35, and 34 months, respectively, with major delays observed in 2023 (64-70 months). Post-reform (2024-2025), the lag shortened to 27, 21, and 20 months, aligning with 2021-2022 levels **(Figure 1)**.

FIGURE 2. MEAN TIME INTERVALS (MONTHS) FROM MARKETING AUTHORIZATION TO REIMBURSEMENT ACROSS MARKETS, 2021–2025



	Pre-reform (2021-23)	Post-reform (2024-25)
JP	11	10
DE	7	12
FR	5	10
UK	12	13

The mean reimbursement time in Japan and the UK was ~6 months longer than the EU average pre-reform. Post-reform, Japan remained stable, while EU reimbursement timelines got longer **(Figure 2)**.

TABLE 1. MEAN LAUNCH PRICES AND ONE-YEAR PRICE CHANGES ACROSS MARKETS, PRE- AND POST-REFORM

	Pre-reform (2021-23)		Post-reform (2024-25)	
	Mean launch price (EUR)	1-Year post launch price change	Mean launch price (EUR)	1-Year post launch price change[b]
JP	6,509	-25%	3,047	-18%
DE[a]	11,013	-15%	6,233	-17%
FR	11,124	-12%	6,158	-17%
UK	16,232	-24%	12,281	-19%
US	19,671	+4%	10,372	+2%

a. 1-year post AMNOG to exclude free pricing period. b. 1-year price change data not available for 2025 drugs

Compared to the pre-reform period, mean launch prices declined across all markets following the reform. Japan had the lowest launch prices and marginally larger price reductions, improving from -25% to -18% post-reform **(Table 1)**.

CONCLUSION

Japan's 2024 pricing reform has yet to demonstrate a meaningful positive impact on access to innovative medicines. While post-reform (2024-25) regulatory timelines improved compared with the unusually long delays in 2023, they remained similar to 2021–2022 levels. Reimbursement timelines showed no improvement, and Japan continued to exhibit lower launch prices and greater post-launch price erosion than peer markets. These findings highlight the enduring influence of cost-containment policies on market access. However, it may be premature to judge the reform's full effects. Continued monitoring of larger post-reform cohorts will be essential to determine whether Japan can balance timely patient access with a more sustainable and competitive environment for innovation.

References
1, PMDA (Pharmaceuticals and Medical Devices Agency) (2023), "Drug Pricing System in Japan – Annual NHI Price Revisions,". 2. Pharmaceutical Technology (2024), "Japan FY2024 Pricing Reform Expected to Favour New Listed Innovative Drugs,". 3. The Lancet (2024), "Challenges Introduced by Japan's Drug Pricing Policy,". 4. EFPIA Japan (2024), "Joint Statement on Drug Lag and Drug Loss," 5. NHSA Chuikyo (2024), "Reform of Japan's Drug Pricing Rules," 6. MHLW (Ministry of Health, Labour and Welfare) 7. FDA (U.S. Food and Drug Administration) , "Drug Approval and Databases," 8. EMA (European Medicines Agency) 9. MHRA (Medicines and Healthcare products Regulatory Agency)