RWD142

# Analysis of Implementation and Termination Characteristics of Managed Entry Agreements for New Drugs Under Taiwan's National Health Insurance System

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## INTRODUCTION

Managed Entry Agreements (MEAs) are confidential contracts between pharmaceutical manufacturers and Taiwan National Health Insurance (NHI) to mitigate uncertainties in financial impact and clinical efficacy, particularly for high-cost drugs or those approved through accelerated regulatory pathways. While MEAs are increasingly used to expedite patient access and share reimbursement risk, little is known about their execution and termination patterns, especially after Taiwan's MEA policy was implemented in 2018.

## OBJECTIVES

This study investigated the implementation and termination characteristics of Managed Entry Agreements (MEAs) for new drugs reviewed by Taiwan NHI from 2019 to 2023, and examined factors associated with MEAs adoption. We focused on three research questions:

1. Trends and types of MEA adoption over time
2. Termination outcomes of MEAs
3. Factors associated with the adoption of MEAs

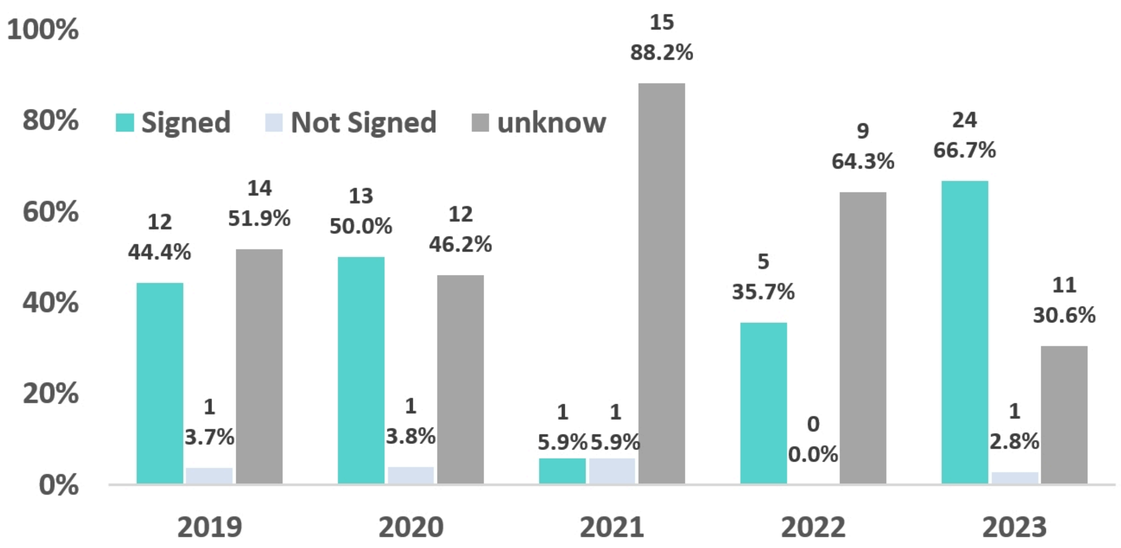
## METHODS

A cross-sectional retrospective study was conducted using publicly available new drug cases from NHI committee meeting records for 2019 to 2023. The MEA characteristics and drug characteristics were analyzed. The MEA characteristics included MEAs signing status, types (financial-based vs. outcome-based), and termination, while drug characteristics included pivotal trial phase, innovation class, ATC classification, and estimated 3rd- and 5th-year financial impact. Chi-square tests identified associations between MEA and drug characteristics.

## RESULTS

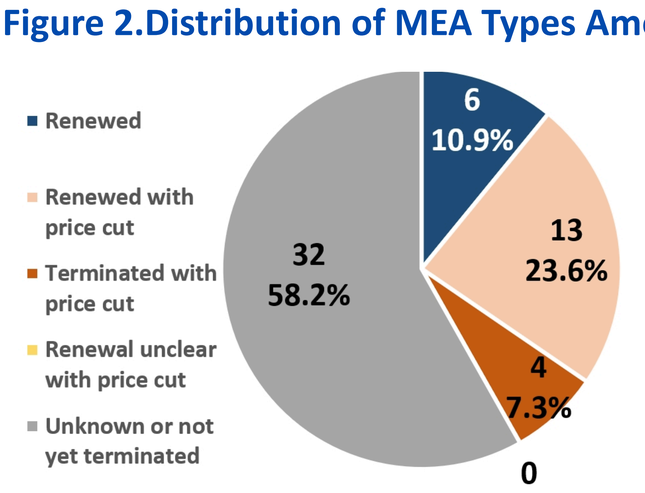
A total of 120 new drug cases were included. Of these, 55 (45.8%) signed a MEA, 4 (3.3%) did not, and 61 (50.8%) had unknown status due to confidentiality.

### Figure 1.Yearly trend of MEA status (2019–2023).



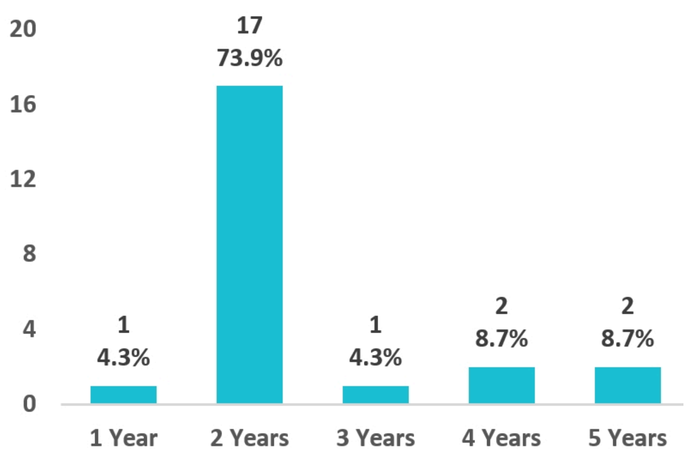

Between 2019 and 2023, the MEA signing rate showed a fluctuating trend, with a sharp drop in 2021 (5.9%) and a peak in 2023 (66.7%).
Unknown status was around half with a exceptional high in 2021 (88.2%) and decreased significantly in 2023 (30.6%).

### Figure 2.Distribution of MEA Types Among Signed Cases (n = 55)




Most MEAs were either renewed with a price cut or had a unknown termination status, suggesting pricing pressure and limited transparency.

### Figure 3.Distribution of MEA Agreement Durations (n = 23)

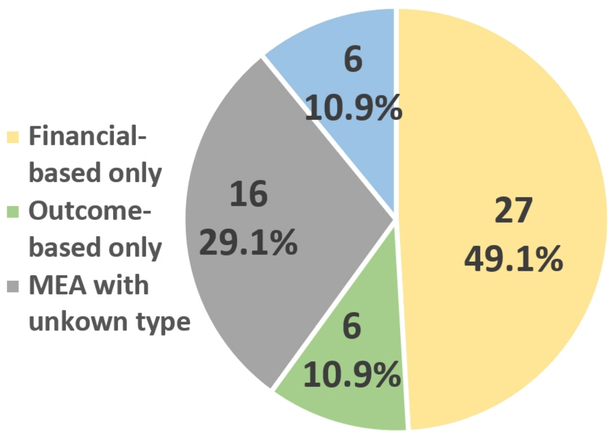



Among the 23 cases, 17 (73.9%) were signed for a 2-year duration.

Notably, one case—PG2 Lyo. Injection 500mg (Whity)—was signed for only 1 year.

The remaining five cases were evenly distributed across 3-, 4-, and 5-year durations.

### Figure 4.Termination Outcomes of Signed MEAs (n = 55)




Financial-based agreements accounted for nearly half of all confirmed MEAs (49.1%), while outcome-based and dual-type agreements were 10.9% respectively.

Notably, 29.1% of agreement types was undisclosed.

### Table1.Heatmap of MEAs Types by Year (2019–2023)

| Financial-based MEAs | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|---|
| Fixed discount agreement | 6 | 2 | 0 | 2 | 8 |
| Cost-sharing agreement | 1 | 0 | 0 | 0 | 0 |
| Patient-level volume cap | 0 | 2 | 0 | 0 | 0 |
| National-level expenditure cap | 4 | 2 | 0 | 2 | 6 |
| Detailed agreement unknown(financial-based) | 0 | 2 | 1 | 1 | 1 |
| **Outcome-based MEAs** | | | | | |
| Overall survival guarantee agreement | 0 | 0 | 0 | 0 | 0 |
| Disease progression delay guarantee agreement | 0 | 0 | 0 | 0 | 0 |
| Clinical outcome-based rebate agreement | 0 | 0 | 0 | 0 | 0 |
| Detailed agreement unknown(outcome-based) | 0 | 2 | 0 | 3 | 7 |
| **Unknown agreement type** | 0 | 5 | 0 | 0 | 6 |

Nearly half of the agreements were signed in 2023. Fixed discount and price-cap schemes were the most common.
All 12 efficacy-based MEAs lacked disclosed subtypes. Eleven cases had unknown agreement types.

### Table 2. Factors Associated with MEAs Signing (Chi-square test)

| Variable | Signed, n (%) | Not Signed or Unknown, n (%) | Chi-square Test $\chi^2$, (p-value) |
|---|---|---|---|
| **Drug Classification** | | | **21.7,(0.0014)*** |
| New chemical entity | 53(96.4) | 41(63.1) | |
| New administration | 0(0.0) | 2(3.1) | |
| New efficacy | 2(3.6) | 6(9.2) | |
| New formulation | 0(0.0) | 16(24.6) | |
| **Innovation Classification** | | | 10.2,(0.1161) |
| Category 1 | 13(23.6) | 7(10.8) | |
| Category 2A | 27(49.1) | 29(44.6) | |
| Category 2B | 13(23.6) | 29(44.6) | |
| First-in-global launch | 2(3.6) | 0(0.0) | |
| **Pivotal Trial Phase** | | | **26.1,(<.0001)*** |
| Phase 2 | 11(20.0) | 0(0.0) | |
| Phase 3 | 43(78.2) | 49(75.4) | |
| Unknown | 1(1.8) | 16(24.6) | |
| **ATC Code** | | | **33.5,(<.0001)*** |
| Oncology drugs | 32(58.2) | 6(9.2) | |
| Non-oncology drugs | 23(41.8) | 59(90.8) | |
| **Financial Impact in the 3rd year** | | | **34.4,(<.0001)*** |
| ≤ NT$50 million | 14(25.5) | 49(75.4) | |
| NT$50M ~ 200M | 26(47.3) | 9(13.9) | |
| > NT$200 million | 15(27.3) | 7(10.8) | |
| **Financial Impact in the 5th year** | | | **30.4,(<.0001)*** |
| ≤ NT$50 million | 12(21.8) | 45(69.2) | |
| NT$50M ~ 200M | 24(43.8) | 12(18.5) | |
| > NT$200 million | 19(34.5) | 8(12.3) | |

The analysis revealed that MEAs were more likely to be signed for new chemical entities, oncology drugs, and those supported by Phase 3 trials.

A higher financial impact was also significantly associated with MEA signing, whereas innovation classification showed no significant relationship.

While most MEAs were for Phase 3 drugs, the 100% MEA rate in Phase 2 cases suggests higher use when evidence is less mature.

## CONCLUSIONS

✓ MEAs signing rates increased steadily from 2019 to 2023.

✓ Financial-based agreements remained the most common, while outcome-based ones showed gradual growth.

✓ Most agreements were renewed upon expiration—often with price reductions—or had undisclosed termination outcomes.

✓ MEAs adoption was significantly associated with oncology drug classification, and higher estimated financial impact.

✓ Due to the confidential nature of MEAs, the findings are based on publicly available data and may not fully reflect the complete landscape.

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