The Discrepancy in Real-World Evidence of New Drug Expenditure between Actual and Estimated Values from Manufacturers and Government Agencies in Taiwan

HPR7

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OBJECTIVE

Budget impact analysis is widely adopted in many countries where health technology assessment is implemented in new drug pricing and reimbursement. We aim to examine the real-world evidence in differences of budgetary impact stemming from existing applications and administrative decision-making.

METHOD

Reports of new drug pricing applications were extracted from the official website of the National Health Insurance Administration between 2014 and 2017. The estimated budgets from pharmaceutical manufacturers and the CDE/HTA agency were derived as the primary outcome. The real-world drug expenditure was also derived. The estimation of total expenditure was adjusted by the final approved new drug unit price. Adjusted predicted drug expenditures and the real-world expenditures provided by both were compared over a five-year time span. Common one-sample and two-sample t-tests, along with signed rank and Wilcoxon Rank Sum tests, were used.

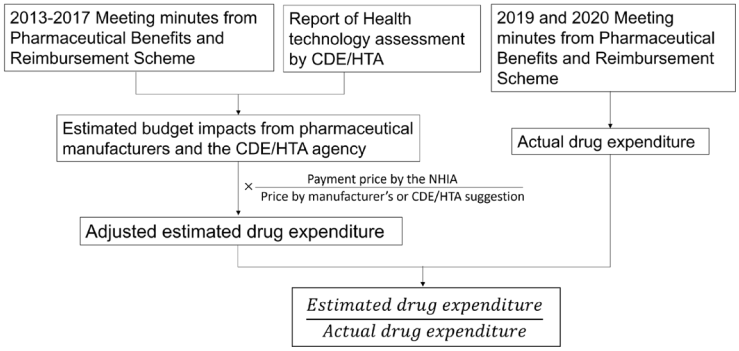
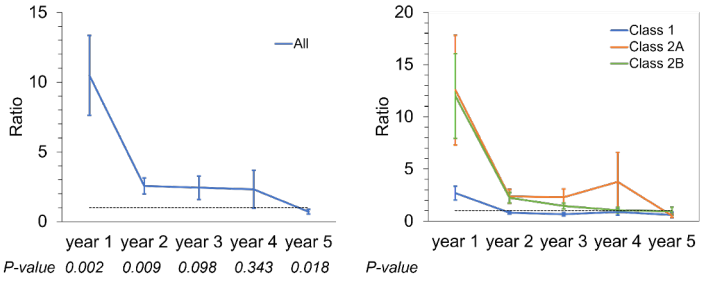
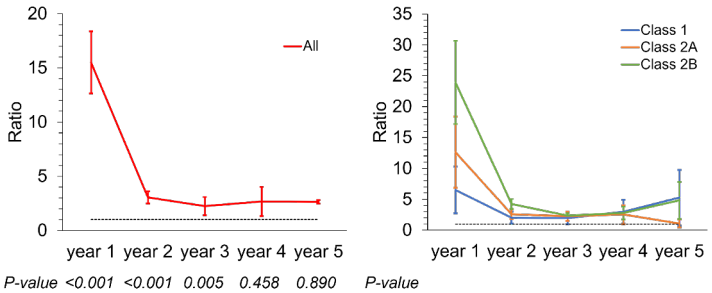


Figure 1. Flowchart of study.



P-value	year 1	year 2	year 3	year 4	year 5
All	0.002	0.009	0.098	0.343	0.018
Class 1	0.039	0.195	0.102	0.625	0.500
Class 2A	<0.001	0.048	0.133	0.850	0.063
Class 2B	<0.001	0.042	0.217	0.844	0.438

Figure 2. The ratio of the manufacturer's estimated drug expenditure to the actual drug expenditure.

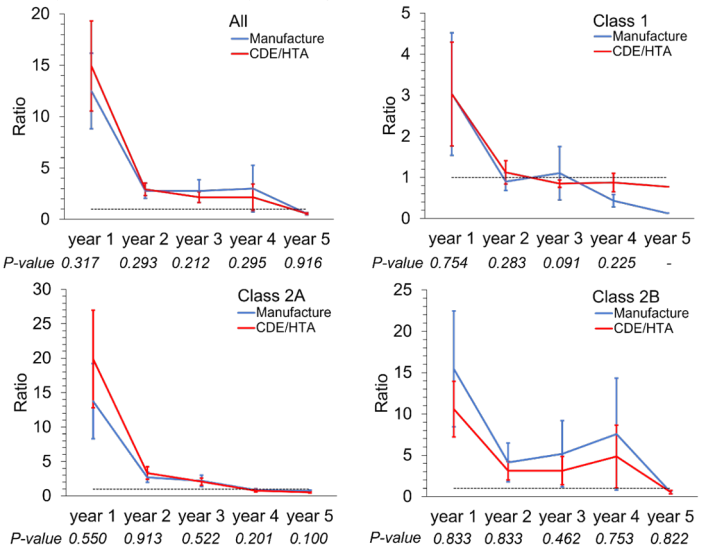


P-value	year 1	year 2	year 3	year 4	year 5
All	<0.001	<0.001	0.005	0.458	0.890
Class 1	0.031	0.781	0.813	0.625	1.000
Class 2A	0.002	0.102	0.888	0.340	0.129
Class 2B	<0.001	<0.001	<0.001	0.125	0.375

Figure 3. The ratio of the CDE/HTA's estimated drug expenditure to the actual drug expenditure.

RESULTS

From 2014 to 2017, 42 cases with complete expenditure information were derived and analyzed. All the budget impact estimation were higher in both manufactures and CDE/HTA as compared to the actual expenditure (ratio > 1) but year 5. There is no estimation difference between manufactures' and CDE/HTA for all five years spans, though CDE/HTA seems to have larger estimation in year one but lower in year 3 to 5. In year one, the budget impact estimations were higher than the actual expenditures for all three classes. The estimation of budget impact of class 1 drugs were all similar to the actual ones from year 2 to 5 between manufactures and CDE/HTA. For class 2A drugs, budget impact estimation are all identical between manufactures and CDE/HTA from year 2 to 5. But they are higher in manufactures for class 2B.



P-value	year 1	year 2	year 3	year 4	year 5
All	0.317	0.293	0.212	0.295	0.916
Class 1	0.754	0.283	0.091	0.225	-
Class 2A	0.550	0.913	0.522	0.201	0.100
Class 2B	0.833	0.833	0.462	0.753	0.822

Figure 4. The comparison of the ratio between the estimated drug expenditure by the manufacturer and the CDE/HTA, and the actual drug expenditure.

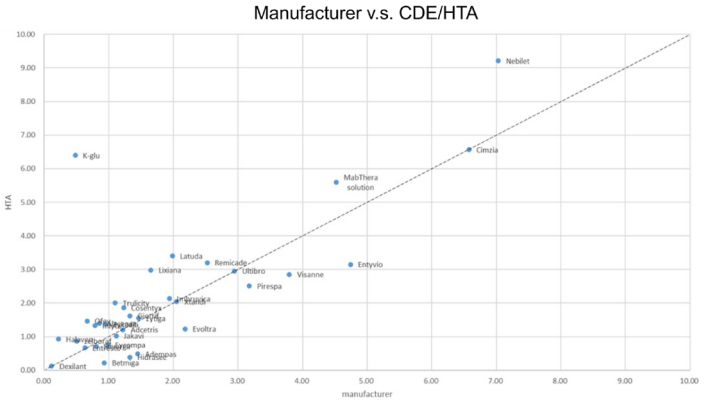


Figure 5. The comparison of the estimated drug expenditure between the manufacturers and the CDE/HTA in each drug.

CONCLUSION

The estimated new drug expenditures in budget impact analysis from both the manufacturer and the government agency were inconsistent with the actual expenditures in the first year, the actual budget impact were lower due to practical reasons such as the timing of new drugs delivery. For class 1 drugs, the estimation of budget impact from CDE/HTA were almost identical to the actual ones between year 2 to 5. Both manufacturers and CDE/HTA estimations were almost identical for class 2A from year 2 to 5, but manufacturer's were higher than CDE/HTA for class 2B. The budget impact analysis were mostly similar for class 2A drugs from year 2 to 5.