UNFOLD THE MYSTERY OF PRICE NEGOTIATION IN CHINA: HOW REIMBURSEMENT PAYMENT STANDARD WAS FORMULATED

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Objective

- Before 2017, high-price innovative drugs were generally absent from the National Reimbursement Drug List (NRDL) due to scarce update opportunities and inadequate access mechanism in China. Since 2017, the Payer (National Healthcare Security Administration, NHSA) has initiated national price negotiation for high-price innovative drugs. This research aims to understand how the reimbursement payment standard (RPS) was formulated in China NRDL negotiation.

Methods

- This analysis includes secondary research of previous negotiation processes and results and is supplemented with primary research with national payers and other stakeholders (KOL, pharmacologist and HEOR expert) to assess the negotiation mechanism.

Result

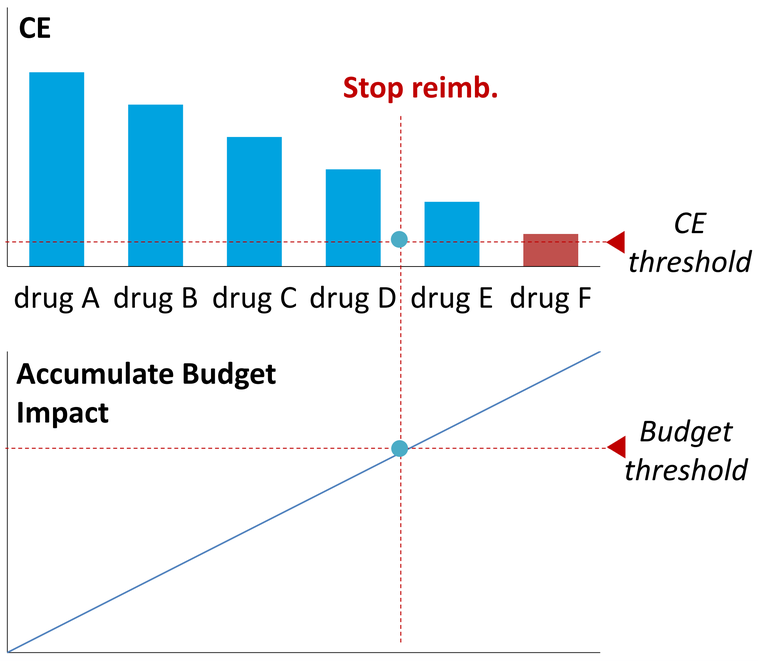
- In the process of RPS formulation, pharmaceutical companies submit materials as required by the Payer and the Payer reviews the materials together with stakeholders.
- There are six crucial factors determining the RPS: 1) clinical advantage over reference product; 2) net price after Patient Assistance Programs (PAP); 3) negotiation price with provincial and city insurance administration, called Critical Disease Insurance (CDI) ; 4) international price reference (IPR) of 12 selected countries and regions; 5) Cost Effectiveness Analysis (CEA), and 6) Budget Impact analysis (BIA) (Figure 1) .

Figure 1 **Six crucial price impact factors are combined to determine the final reimbursement payment standard after negotiation**

	Factors	Details	Examples
Pricing	International Pricing Reference	• Highly referencing the price of 12 comparison countries and regions, RPS is getting closer and closer to the lowest IRP price in 2018	• **Novoseven, Noxafil, Fosrenol, Victoza:** RPS within ±5% of Taiwan and Korea price • **Giotrif, Sutent, Xalkori's** RPS is 2nd lowest worldwide
	PAP	• Usually no more than the PAP net price	• **Take off PAP:** Tagrisso (-71%, 4+8 then 3+PD (progressive disease)), Faslodex (55%, 6+6) • **Use mPFS to calculate:** Mabthera (-36%, 4+4)
	Critical Disease Insurance (CDI) negotiated price	• No more than PRDL or CDI price, normally much lower than CDI price	• **Inlyta, Xalkori:** 3 times price cut rate of CDI price • **Zelboraf, Imbruvica**: 2 times price cut rate of CDI price
HEOR	Cost-effectiveness Analysis (CEA)	• ICER < 3*GDP per capita, compare to competitors', to better prove product CE	• **Giotrif, Tagrisso, Focus V**: price cut % of TKIs for NSCLC and ICER number is proportional
	Budget Impact Analysis (BIA)	• Compare to competitors', to better prove lowered cost, AE or other cost incremental	• **Herceptin:** largest budget impact among oncology drugs, ~0.4 Bn USD, might facing more cut in 2nd negotiation • **Lucentis:** largest BI in non-oncology drugs, around 100 Mn USD, also facing further cut, in additional to the new indication launch
Competition	Clinical advantage over reference product	• Within same disease areas: • 1) In the same MOA • 2) Among different MOAs	• **Brilinta:** comparable RPS with Clopidogrel based on daily cost • **Giotrif:** price after cut is similar to the price of Tarceva/ Iressa/ Conmana

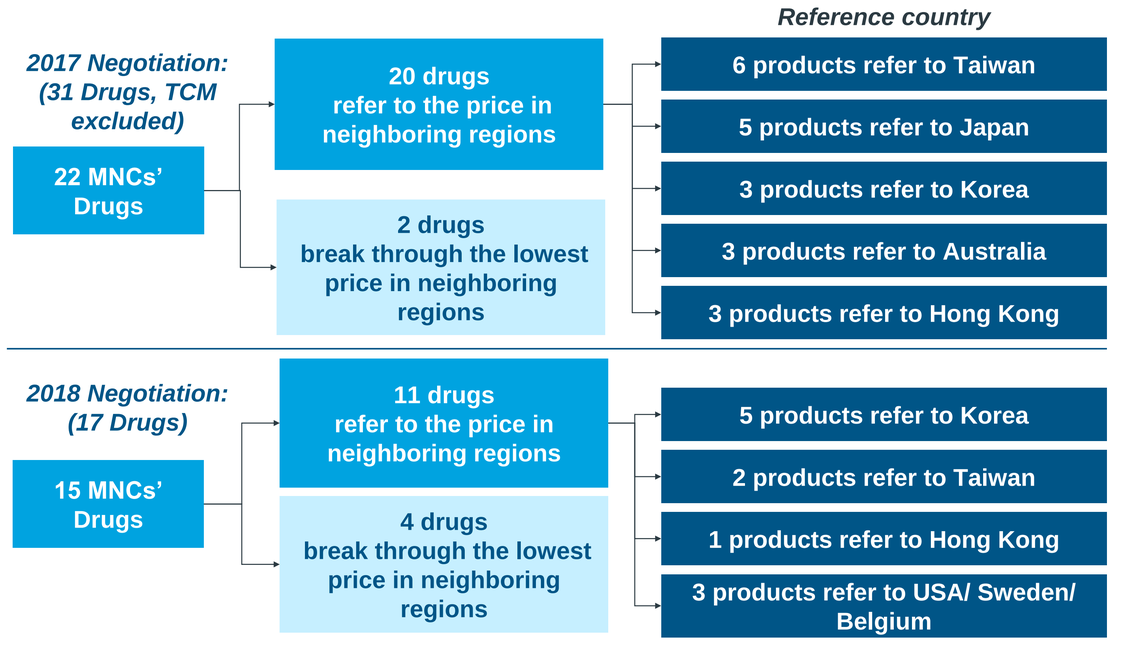
- Among all the factors, the most important are IPR, BIA and CEA as the decision was made under budget constraint.
- **BIA** plays the most important role in negotiation. The payers don't have a definitive threshold, but budget impact over 1 billion USD is considered as significant increase. Drugs with higher cost-effectiveness and lower budget impact will be prioritized to reimburse (Figure 2).
- **CEA:** though not officially published, ICER is required to be less than 3 times of GDP per capita (9,608 USD). However, due to insufficiency of real-world evidence, inaccurate CEA result with doubtful third-party CEA credibility, lack of systematic methodology and official guide and uncertain CEA evaluation administration department, the execution and evaluation level of CEA is still under development.
- **International Price Reference:** 12 countries and regions including Japan, Korea, Hong Kong, Taiwan, Macau, Australia, USA, UK, Canada, Germany, France and New Zealand. Taiwan, Korea, Japan and HK are the regions have been most frequently referred to (Figure 3). In 2019, Turkey, the country with extreme low price and Italy have been added and Australia and New Zealand have been removed, which indicates the trend of RPS, closer to the lowest worldwide price.

Figure 2 **Decision mechanism schematic diagram based on comprehensive analysis of CE and BI**



- Due to the budget constraint, the government prefers to prioritize the drugs that have high cost-effectiveness and low budget impact on the fund, and will focus on the HEOR review of the drugs with large usage and doubtful clinical efficacy. Drugs with low CE and high BI will be likely to be fail in negotiation.

Figure 3 **Statistics of RPS reference country of MNC products in 2017 and 2018**



Conclusion

- The RPS is formulated by multiple stakeholders and includes review of multiple interrelated factors. Among them, HEOR plays the most significant role in RPS formulation.