How health technology reassessment can support disinvestment in China's national drug reimbursement list

A requirement to assess actual use of reimbursed medicines would enable transparent, documented, evidence based decisions on disinvestment, say **Lizheng Shiand colleagues**

Pharmaceutical expenditure has been an important focus in China for the past three decades, particularly because of its role in the rising cost of healthcare and access to essential medicines. Basic health insurance has also expanded greatly since 2003 to cover different populations (eg, employees, rural populations, and urban residents). In 2019, medicines represented around 34% of total healthcare costs in China,[1] higher than the average for countries in the Organisation for Economic Cooperation and Development. In an attempt to contain costs, the National Healthcare Security Administration (NHSA), which runs China's health insurance system, has decided to remove medicines that provide low value from its national drug reimbursement list. However, decisions are not required to be based on a formal assessment of a drug's performance.

We examine how health technology reassessment (HTR) has been used to identify and phase out medicines from the list and how its use can be increased to improve disinvestment decisions in China and elsewhere.

Challenges of rising drug costs

There have been six updates to the national reimbursement drug list since 2000, and the number of drugs has more than doubled, from 1308 to 2860 (fig 1). Some of the expansion has arisen from widening coverage of the scheme. For example, work related injury coverage was added in 2004 and the national essential medicine list in 2009. Price negotiation for novel drugs was piloted in 2017[2] and expanded in 2019, with subsequent annual price negotiations (2020, 2021). This resulted in a growing number of new medicines being included in the list.

The reimbursement list is an important step towards increasing access to expensive medications. Provinces in China are required to implement the most recent list, although they are allowed to delete, add, or substitute up to 15% of the medications to accommodate differences in economic development, insurance funding pools, and reimbursement rates. The resulting provincial lists further amplify the inconsistencies in the evidence making process for medicines coverage across more than 30 provincial authorities.

In addition to budgetary impact analysis to better manage list expansion,[3] the NHSA is also starting to remove drugs and renegotiate prices because of the escalating healthcare costs in China and an economic slowdown in the past few years. The overall goal of the disinvestment initiatives is to help keep the overall budget for the reimbursement list neutral. In other words, the budget increases for the new listings should be offset by the saving of disinvestment activities.

Potential role of HTR in disinvestment

Health technology assessment (HTA), including pharmacoeconomic evaluation guidelines, has contributed to 30 years of evidence informed decision making in China, most recently as part of analyses to support price negotiation for medicines added to the reimbursement list in 2017 and 2019.[4]

A similar process, health technology reassessment, can help manage use of medicines on the list and identify those for disinvestment, and it should become standard practice in review of the reimbursement list.[5 6] The goals of HTA and HTR are the same: the optimal use of health technologies. For the national reimbursement list, "optimal" refers to getting the best health value for the cost of medicines. However, HTR differs from HTA as it focuses on actual use, which calls for good reviews of drug use in real world practice.

Using HTR to inform disinvestment decisions is not straightforward and incurs more challenges than using HTA for new investments or new listings.[7] The HTR methods must consider how medicines are currently used, in terms of evidence of clinical ineffectiveness or inappropriate use,[8] across populations that are more heterogeneous than clinical trial populations.

Pilot disinvestment activities in China

The NHSA embarked on large scale disinvestment from the national reimbursement list using its internal monitoring administrative review process in 2019 (table 1). This review resulted in the delisting of 150 medications, half of which had had their licences withdrawn by China's drug regulator, the National Medicine Product Administration, because of poor clinical effectiveness or pervasive misuse. A list of 20 drugs to be monitored for "irrational use" was officially released in July 2019, including glycosides, alprostadil, and oxiracetam. The total sales of these 20 drugs exceeded ¥60bn (£7bn; €8bn; $8bn). These drugs were also included in the 150 removed from the reimbursement list, reducing the financial burden on the national health insurance fund.

The NHSA has decided to extend the administrative review process to target variations between the national and provincial reimbursement lists as future disinvestment opportunities. It is using disinvestment to eliminate the provincial lists in phases (40%, 40%, and 20%) over

KEY MESSAGES

- China has started initiatives to remove medicines from its national reimbursement drug list
- Health technology reassessment (HTR) was not listed as a criterion for disinvestment decisions
- Greater use of HTR can help determine the real life effectiveness of medicines
- Effective communication of HTR evidence is essential to ensure evidence based decisions

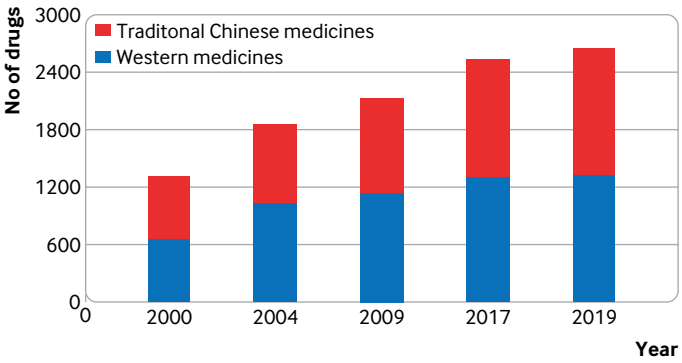

Fig 1 | Expansion of China's national drug reimbursement list, 2000-21

three years (2020-22). Criteria published in July 2020 specify two categories of disinvestment: compulsory disinvestment (eg, drugs withdrawn from the market or with poor risk: benefit profile) and conditional disinvestment (eg, drugs with uncertain cost effectiveness or poor performance within a therapeutic class). Price renegotiation for 14 drugs being considered for conditional disinvestment from the reimbursement list was piloted in 2020. Public hospitals spent ¥36bn on these 14 drugs in 2019, and the price of the drugs was reduced by an average of 43.5% after renegotiation. Importantly, eight of the 14 drugs were traditional Chinese medicines; NHSA leadership has specifically indicated the need to reassess reimbursement of traditional medicines.

The pilot disinvestment of traditional Chinese medicines contributed to evidence making in health policy, with real world data on effectiveness, safety, and cost effectiveness as well as budget impact analysis particularly important in generating evidence. These disinvestment activities have accelerated in the past two years, according to the NHSA's announcements. In 2021, in addition to the compulsory delisting of 11 medicines, 32 drugs were eligible for reassessment after the contract period for their original price negotiation expired. In 2022, a total of 145 medicines were considered for price renegotiations. The price renegotiations were primarily based on the actual budget impact rather than the predicted budget impact analysis used during the initial price negotiations.

Although the importance of scientific and economic evidence was mentioned in the pilot disinvestment through price renegotiation, the decision making procedures for adjusting the national reimbursement list remain unclear because HTR processes have been used only implicitly and subjective expert opinion continues to dominate in appraisal. By contrast, HTA is used routinely for initial price negotiation of all newly listed medicines.

Greater use of the HTR framework in guiding disinvestment from the national reimbursement list will help ensure optimal use of health technology, as recommended by the HTA international policy forum.[9] The general HTR framework consists of three broad phases and six iterative stages[10]: identification of disinvested drugs, prioritisation, evidence synthesis, policy or practice recommendation, policy or practice implementation, and monitoring and evaluation. For instance, we reassessed the evidence for the effectiveness of antihypertensive medicines in the reimbursement list. Nearly half of the listed antihypertensive medications had insufficient evidence of effectiveness.[11] While this finding raised awareness of the opportunities for HTR to improve the reimbursement list, the challenge remains in using the HTR process to support disinvestment decisions and optimising clinical pathways in the future.[12]

To harness the potential power of HTR to reassess technologies currently in use, the outputs and recommendations must be translated into practice.[13] This translational step is the most difficult. A recent international review found that of the 16 organisations that had developed an HTR programme, just one was able to directly implement the HTR decision, 10 had advisory roles, and five had no input.[14]

We also examined the barriers and facilitators in translating HTA evidence into policy in China.[15 16] We found that despite policy makers (evidence users) and researchers (evidence generators) having different perceptions of HTA evidence, both groups agreed on expanding collaborations in research development and presentation of evidence in easily understood language. Both groups identified close contact between the research unit and policy making department and relevance of HTA to policy making as facilitators of knowledge translation. For researchers, the practicality of HTA reports and the presentation of evidence in easily understood language can facilitate knowledge transfer. Policy makers, on the other hand, considered an overly scholastic presentation of HTA evidence to be an obstacle to effective knowledge translation. Thus, improved communication of HTR evidence between researchers and policy makers behind disinvestment decisions could contribute to the uptake of evidence

Table 1 | Pilot disinvestment activities in China's national reimbursement drug list (NHSA information)

Year	No of medicines identified for disinvestment	Method of identification	Disinvestment category	HTR	Type of HTR
2019	150, including 20 being monitored for irrational use	NMPA misuse surveillance list	Compulsory delisting	Yes	Safety and effectiveness
2020	14	NHC's list of key drugs monitored for irrational drug use	Conditional disinvestment by price renegotiation	Yes	Effectiveness, safety, cost effectiveness, budget impact
2021	11	NHSA's list of low value and low use medicines*	Compulsory delisting	Yes	Effectiveness, safety, cost effectiveness, budget impact
	32 for price renegotiation	NHSA contract expiration (drugs newly listed in 2017)	Conditional disinvestment by price renegotiation	Yes	Budget impact, effectiveness, safety, cost effectiveness,
2022	145 for price renegotiation	NHSA contract expiration (drugs newly listed in 2018 and others expiring by end of 2022)	Conditional disinvestment by price renegotiation	Yes	Budget impact, effectiveness, safety, cost effectiveness

HTR=health technology reassessment, NMPA=National Medicine Product Administration, NHC=National Health Commission, NHSA=National Health Security Administration.
*Low value was determined if there are better alternatives in the list; low use was determined by usage review for the reimbursement list.

informed policies and recommendations that result from an HTR process. Sharing disinvestment initiatives across countries is also important because the success of disinvestment initiatives by HTA agencies has been mixed globally.[17 18]

Recommendations for better disinvestment decisions

Because HTR focuses on drugs already included in the reimbursement list and their actual use in clinical practice, more research is needed to explore the feasibility and strength of using administrative data (eg, electronic health records, insurance claims, and patient registries) to identify and prioritise medicines for HTR at a population level.[19] Furthermore, a systematic approach using real world evidence, literature review, and economic evaluation needs to be developed to move the assessment of medicines in China's reimbursement list on to disinvestment actions through either compulsory delisting or price renegotiations.

It is critical to collaborate with NHSA in translating HTR evidence into easily understood language. The operationalisation of knowledge translation should be aligned with incentives to improve the reimbursement list's administrative monitoring and review process for disinvestment decisions. Transfer of HTR evidence can play an important part in incorporating HTR recommendations into the NHSA's monitoring and review processes. This can be achieved by extending the HTA knowledge translation theories, models, and framework that have been tested in China. Such steps will contribute to shifting reliance on expert opinions and achieving optimal use of medicines throughout their life cycle.

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