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• 中文摘要	<p>自 1995 年全民健保開辦以來，藥品費用由 1996 年的 622 億元，2003 年的 944 億元，逐年增加至 2007 年的 1097 億多元，約佔健保醫療費用的 24.5%至 25.5%之間，較美國的 15%高。同時，因為健保財源有限、人口老化及疾病嚴重度等原因，造成藥費龐大支出，因此節制藥費成長成為目前健保局的主要目標之一。目前各國的藥品政策主要為規範給付藥品項目，以及管制藥品價格兩大方向。在規範藥品是否納入給付範圍方面，各國採行的主要方法包括正面表列與負面表列兩種方式。在藥價控制上，美國以外的多數國家均對藥品價格採取管制措施，由政府或保險人與藥廠議定藥品價格，採用的方式包括：國際價格比較定價、參考類似藥品定價、依成本定價、藥價凍結、藥品價量協議等。本研究擬由 MEDLINE、PubMed、SCOPUS....等大型醫學相關學術資料庫中，徵集並歸納彙整 2000 年以來，美國、英國、加拿大、澳洲、德國、法國、日本、南韓、義大利等國家的藥品支付制度與藥價政策相關文獻。此外，將分別於本計畫進行第 3 個月及第 6 個月時各召開一次專家會議，請專家閱讀上述分析結果，再針對臺灣未來藥品支付制度、藥價政策及藥品給付範圍等給予建議。本研究最後給予建議如下：1.政府應加強 HTA 的功能，以藥品的價值為基礎來決定給付及價格，如同加拿大、澳洲及英國等，訂定一套公平、合理且適合台灣的藥物經濟評估指南，並學習韓國的做法，規定申請新藥給付的廠商需根據評估指南，提供如成本效益及預算衝擊分析等藥物經濟學數據及評估過程，作為政府決定藥物收載及核價之依據。2.因多數專利藥品屬漸近式創新性藥品，故政府可學習加拿大做法，針對創新性新藥的分類、定義及核價原則給予更加明確規範，才不會訂價時造成混淆困擾，同時亦可提供藥廠確切之依據。3.藥品若屬突破性新藥，政府應給予高價，以獎勵研發，同時若新藥引進速度較他國快，也需考慮以少數國際藥價為參考來核價的合理性。另外，可學習英國作法，針對某些藥品與廠商簽訂 risk-sharing</p>		

agreement, 以分攤使用新藥之不確定性風險。若屬療效類似新藥, 政府可學習日本, 考量新藥與類似品比較下多方面的優點來核價, 並且在選取類似品為核價基準時, 可探討類似品的價格是否為合理。 4.政府可考慮針對同治療類別或是療效類似之藥品訂價實施參考藥價制度, 除可間接管控藥品給付價格外, 亦可藉由廠商的自由訂價及民眾的藥品差額負擔, 促進藥品市場的價格競爭, 並鼓勵民眾使用價格較低的藥品。不過, 政府也需確保以參考價訂價之藥品的治療效果, 並教育民眾低價藥品也有良好之療效, 藉此減少民眾對於公平性之擔憂, 同時導正民眾用藥觀念, 及給予民眾自由選擇用藥的空間。

Since the national health insurance has started in 1995, the pharmaceutical expenditure increases from 6,220 million in 1996 and 9,440 million in 2003 to 10,970 million in 2007, which represents approximately one-quarter of the total NHI expenditure and is higher than 15 percent of the pharmaceutical expenditure of America. Meanwhile, due to limited financial resources for NHI, population aging and disease severity, pharmaceutical costs become extremely high. Thus, to control on the growth of pharmaceutical expenditure becomes one of the primary goals for the Bureau of National Health Insurance. The pharmaceutical policies in most countries are mainly to regulate the reimbursement list and control the pharmaceutical price. To define whether the pharmaceuticals can be reimbursed or not, two methods, positive lists and negative lists are adopted. For the price control, most countries besides America adopt statutory pricing and also negotiate price through governments or insurers with manufactures. Procedures they used to set and control the pharmaceutical price include international price comparison, reference pricing, cost-plus pricing, the pharmaceutical price survey, price freeze and price-volume agreement as well. The study reviews and analyzes the literatures concerning the pharmaceutical reimbursement and pricing policy from 2000 within an international context through the literature searched from large databases, such as MEDLINE, PUBMED and SCOPUS. The study focuses on literatures in America, United Kingdom, Canada, Australia, Germany, France, Japan, South Korea, Italy, etc. In addition, two expert meetings are held in the third month and the sixth month after the launch of the project. By referring to the analysis of the literature review, experts are expected to provide suggestions with regard to the prospective pharmaceutical reimbursement and pricing policy of Taiwan, and the consequence and impact of the policy revision on Taiwan. The study makes following suggestions. First, governments should strength the role of HTA with the reimbursement decision making and price setting based on the pharmaceutical value. Governments could develop a pharmacoeconomic guideline suitable for Taiwan, and learn from Korea, which requires manufactures to submit the economic evaluation based on the guideline during the application of listing and pricing. Second, due to the circumstances that most of innovative drugs have only gradual innovation but not breakthrough, for the clear definition of the level of therapeutic improvement and the reasonable price setting rule, government should consider the way Canada does. Third, prices for breakthrough drugs should be set higher as a reward for innovation, and should be set with the consideration of the appropriateness when referencing international prices. Prices for drugs with comparable therapeutic effect should be set by considering its safety, efficacy and convenience compared with its comparator as Japan does. Besides, it is worth to define the way to select the comparator and to consider the appropriateness of adopting its price as a reference. Last but not least, for drugs in the same pharmacotherapeutic

- 英文摘要

category or have similar therapeutic effect, government can consider to adopt reference price system which has already been used in several western countries. Under the reference price system, government could not only control pharmaceutical prices indirectly, but also promote competition in pharmaceutical markets as well as give patients incentives to take drugs with lower price. For not being worried about equity in using pharmaceuticals by patients, government should guarantee also educate patients the safety and the effectiveness of drugs with reference price.