



Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal

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ABSTRACT

Background: In Thailand and the US negotiating FTA, the ‘TRIPs-Plus’ is one of the US proposal which would result in an extension of market exclusivity of innovative drugs. In addition, it would foreseeably lead to high and unaffordable medicine prices and inaccessibility to essential medicines.

Objective: To quantify the impact on medicine expense and medicine accessibility.

Methods: Based on 2000 to 2003 Thai Food and Drug Administration (FDA)’s and the Drug & Medical Supply Information Center (DMSIC), costs and accessibility were estimated upon the price and quantity costing between innovative drugs and their generics plus some parameters found from their competitive behaviour. Thereafter, we simulated the 10-year potential additional expense on the 2003 unit price of the patented and monopolized non-patented medicines.

Results: In 2003, the availability of generics helped to save 104.5% of actual expense and the accessibility would increase by 53.6%. By extension of market exclusivity, given that there were 60 new items approved annually, the cumulative potential expense was projected to be \$US 6.2 million for the first year to \$US 5215.8 million in tenth year.

Conclusion: The TRIPs-Plus proposal would result in a significant increase in the medicine expense; and a delay in the increase in drug accessibility via generics. Several options as well as other related mechanisms to help reduce the negative impact are proposed.

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1. Introduction

Since the past decade, the USA has pursued several bilateral and regional Free Trade Agreements (FTAs) with its

trade partners. All such agreements are different in detail and progress, for instance, the agreements with Jordan, Chile, Singapore, Australia, Morocco, Bahrain, the North Americas (NAFTA) and the countries of Central Americas plus the Dominican Republic (CAFTA-DR) have entered into force; the agreements with Colombia, Panama and Republic of Korea are pending by Congressional Approval; the agreements with Peru and Oman are pending on imple-

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