

[学術大会講演録]

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ジェネリック・エッセンシャル医薬品原薬/中間体/原材料の供給危機 —ベトナム/アセアン/沖縄/日本でつなぐ原薬/中間体/原材料の生産も 考慮にいたしたサプライチェーンの強化—

Crisis in Supply-Chain of Active Pharmaceutical Ingredients, Intermediates, and Raw
Materials of Generics and Essential Medicines
—Strengthening Supply Chains That Take into Account the Production of APIs,
Intermediates, and Raw Materials by Connecting Vietnam, ASEAN, Okinawa, and Japan—

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Summary: Currently, Japan's Active Pharmaceutical Ingredients (API)/intermediates of generic/essential drugs are imported from abroad in terms of quantity and product. The main sources of API/intermediates are China and India, but some intermediates used globally are made only in China. For Japan and other countries/regions, a stable supply chain and production of API/intermediates is the basis of human security; however, production is currently dominated by a few hegemonic countries. Furthermore, comprehensive investigations and solutions to obtaining stable supply chains of API/intermediates have not been considered or conducted. Because of the global political/military crisis following the COVID-19 pandemic, prices of raw materials have soared, affecting the global manufacturing industry. API/intermediates of generic/essential drugs are no exception. Securing the supply chain for, including the production of, API/intermediates of generic/essential drugs would become an epicenter of political and diplomatic issues sooner or later because of the conflict between hegemonic countries. Some possible solutions to these issues include: ① Creating/reforming the medical/health care system to avert the supply chain crisis of APIs/intermediates, such as by reducing wasteful/unnecessary prescriptions, improving medical guidelines, and actively using clinical pharmacists. ② Encouraging research and development on manufacturing/production/logistics of generic/essential drug APIs/intermediates/raw materials by reducing associated costs and improving quality through technological innovation. ③ Manufacturing of APIs/intermediates/raw materials with technology transfer in third countries other than China and India. Specifically, we believe that diversifying the supply chain will ultimately help solve the problem of the supply crisis of generic/essential drugs, which significantly affect the people of Japan, ASEAN, and the world.

Key words: active pharmaceutical ingredients, intermediates, essential medicine, generic medicine, supply chain

要旨: 現在、日本のジェネリック医薬品/エッセンシャルドラッグの原薬/中間体は、量的にも品目的にも海外輸入に依存している。原薬/中間体の主な輸入先は中国とインドが主であるが、一部の中間体は世界中でも中国でしか製造していないものもある。日本のみならず、世界の国々・地域において、原薬・中間体の生産を含む安定的なサプライチェーンが人間の安全保障の基盤となっているが、その現状は一部の覇権国が独占しているが現状である。しかし、API/Intermediateのサプライチェーンの問題の包括的な調査と解決方法の検討されていない。コロナ禍に伴う世界の政治・軍事危機により、物価が高騰し、世界の製造業が影響を受けている。ジェネリック/エッセンシャルドラッグの原

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