Tiffany Chen â?? Chair, Taiwan Generic Pharmaceutical Association (TGPA)

> Our message is straightforward: pharmaceutical resilience must be treated as a national priority

05.03.2026

Tags:

Taiwan, TGPA, Generics, Access, Affordability,

The TGPAâ??s Tiffany Chen brings over three decades of experience at the intersection of pharmaceuticals, public policy, and industry development. In her current role, she leads advocacy efforts to strengthen regulatory and reimbursement frameworks, safeguard sustainable margins, and reinforce supply resilience in Taiwan. At the same time, she also works for one of the leading local pharmaceutical companies as pubic affairs director. Under her leadership, TGPA promotes trust in high-quality generics while positioning the sector as a cornerstone of Taiwanâ??s healthcare security and ageing-society preparedness.

Could you outline your professional background and your role at TGPA?

I have spent more than three decades working at the intersection of pharmaceuticals, public policy, and industry development in Taiwan, with a focus on regulatory affairs, industry coordination, and government relations. As Chair of the Taiwan Generic Pharmaceutical Association (TGPA), I represent the collective interests of Taiwanâ??s generic â?? and a small number of biosimilar â?? manufacturers.

My role centres on facilitating constructive dialogue with policymakers and ensuring that regulatory and reimbursement frameworks support both patient access and a sustainable domestic pharmaceutical industry. I work closely with key stakeholders to align industry capabilities with

Taiwanâ??s broader healthcare and economic objectives.

How does TGPA position itself within Taiwanâ??s pharmaceutical and healthcare policy landscape?

Within Taiwan, three major pharmaceutical associations operate. The Taiwan Pharmaceutical Manufacturers Association (TPMA) requires members to have manufacturing capabilities, while the Taiwan Pharmaceutical Manufacturers and Development Association (TPMDA) focuses primarily on innovative drug development and emerging technologies. TGPA, by contrast, has the most diverse membership base.

Of our 80 members, 51 percent are manufacturers, 38 percent distributors and agents, three percent CROs, two percent R&D organisations, and six percent logistics providers. This breadth allows us to represent the full generic medicine ecosystem rather than manufacturing interests alone.

Our core function is advocacy and policy engagement. We work closely with the Ministry of Health and Welfare, the Taiwan Food and Drug Administration, and the National Health Insurance Administration to ensure that regulatory and reimbursement policies support stable supply chains for essential medicines.

TGPAâ??s strategic priorities rest on three pillars. First, we advocate for a stable and predictable regulatory environment that enables manufacturers to maintain high quality standards while remaining economically viable. Second, we emphasise the role of generic and biosimilar medicines in strengthening healthcare affordability and supply resilience. Third, we prioritise communication â?? with both government stakeholders and the public â?? to reinforce trust in the quality, safety, and therapeutic equivalence of Taiwanâ??s generics.

This positioning is particularly relevant given Taiwanâ??s healthcare expenditure structure. Branded medicines account for roughly one-third of volume but approximately 70 percent of total pharmaceutical spending. Generics, by contrast, represent around 70 percent of volume while accounting for just over one-fifth of expenditure. Foreign genericsâ?? share is half of the one-fifth, but local generics still have an essential role to play in cost containment.

However, cost control must be balanced with long-term supply sustainability. Excessive pricing pressure without adequate policy support risks market withdrawal and potential shortages â?? a vulnerability highlighted globally during and after the COVID-19 pandemic. We believe a robust domestic generic sector is not merely a mechanism for short-term savings, but a cornerstone of healthcare resilience, regulatory compliance, and national pharmaceutical security.

At the same time, we continue to highlight the strengths of Taiwanâ??s generic industry â?? strong regulatory governance, consistent manufacturing quality, and a longstanding commitment to patient safety â?? which underpin both public trust and growing international credibility.

How do constrained pricing parameters affect your member companiesâ?? investment capacity and growth trajectories?

We cannot sustain substantial investment given the compressed margins deteriorating annually. The National Health Insurance Administration implements annual price reductions effective each April for both generics and branded products. Branded manufacturers enjoy reasonable zones â?? 15

percent margins below which price cuts do not apply. However, generic competition is severe given the numerous companies competing within modest market parameters.

As a result, investment capacity is constrained across the sector. One of the key challenges is the increasing complexity and stringency of regulatory requirements, particularly in areas such as GMP compliance, pharmacovigilance, and lifecycle management. While high standards are essential, alignment between regulatory expectations and practical implementation timelines is critical. Without sufficient margin flexibility, companies struggle to absorb rising compliance costs while continuing to invest in quality systems, manufacturing upgrades, and new product development.

Substantial transformation has occurred over seven years. Whilst the governing party maintains continuity, presidential transition has brought significant change. Our current president, a physician by training, focuses intensively on healthcare infrastructure, launching the Healthy Taiwan initiative, including substantial cohort programme budgets.

Importantly, the government now recognises generic pharmaceuticalsâ?? strategic importance as a national security imperative. Previously, three to four years ago, we represented the pharmaceutical industryâ??s silent constituency. Regardless of regulatory concerns, we accepted secondary positioning. American, European, and Japanese pharmaceutical associations maintained prioritised government access; we occupied subordinate positions.

Consider patent linkage implementation six years ago through administrative order, replicating US frameworks. Patent linkage represents branded manufacturersâ?? primary mechanism delaying generic market entry. We have endured this regulatory burden for six years, consistently requesting government reassessment of impacts and outcomes.

Currently, we work vigorously to ensure regulatory and reimbursement policies support industry sustainability whilst reinforcing policymaker, healthcare professional, and public confidence in generic quality and reliability.

TGPA emphasises educating the public on the quality and efficiency of generic medicines. What strategies have been most effective?

Clear and consistent communication has been essential. TGPA prioritises evidence-based messaging that explains bioequivalence, regulatory oversight, and real-world outcomes in language accessible to the public. By reinforcing that Taiwanâ??s generics are manufactured under rigorous supervision and meet the same quality standards as originator products, we strengthen public confidence.

Collaboration has also been critical. Working closely with healthcare professionals, patient groups, and academic experts ensures that trusted voices communicate that generics are not only affordable, but safe, effective, and dependable.

Public acceptance of generics is strong. However, prescribing behaviour follows different dynamics. Physician preferences often reflect broader investment structures within the healthcare ecosystem. Having spent 15 years with multinational pharmaceutical companies before joining CCPC, I have seen first-hand how branded manufacturers invest extensively in physician engagement â?? research grants, academic collaboration, and professional development initiatives. Such infrastructure naturally influences prescribing patterns.

Generic manufacturers operate under a different model. We rely on established indications and regulatory approval rather than extensive promotional programmes. Historically, this contributed to a preference for branded products in certain settings. However, as the financial burden on the National Health Insurance Administration has intensified, prescribing patterns have begun to shift. While major hospitals may still favour branded medicines in some cases, clinics increasingly adopt generics due to cost considerations and growing government policy encouragement of their use.

Statistics demonstrate substantially higher generic utilisation in clinics versus large medical hospitals. What explains this divergence?

Hospital prescribers function as employees compensated by institutions receiving National Health Insurance Administration reimbursement. Upon establishing independent clinics, physicians become owners, prioritising business considerations. More affordable products with superior margins assume primary importance in procurement decisions.

Generic preference benefits payers â?? National Health Insurance Administration and the general public â?? plus clinic proprietors. However, prescribers receive no direct benefit, hence human nature, favouring branded alternatives in the absence of economic incentives.

The National Health Insurance Administration operates an exceptional yet fiscally strained healthcare system, given the ageing Taiwanese population. What role could enhanced generic adoption play in easing this strain?

Drug shortages generate enormous impact on public health security. The government recognises that multinational branded manufacturers may exit Taiwan without maintaining supply chain responsibilities. Domestic generic manufacturers remain committed â?? we cannot relocate. When branded companies command 70 percent market share and withdraw, local generics must rapidly compensate, yet immediate capacity expansion proves unfeasible.

The government now encourages local generic manufacturers, prioritising 584 designated essential medicines for supply chain resilience. This strategic reorientation derives from our physician-presidentâ??s familiarity with the healthcare sector. TGPA currently enjoys unprecedented policy engagement â?? government proactively consults us whilst we submit strategic recommendations.

Last November, we delivered ten comprehensive suggestions to the minister, receiving substantial appreciation with indications that all recommendations merit implementation consideration.

Which countries exemplify effective generic pharmaceutical policy frameworks?

Prior to the establishment of Taiwanâ??s National Health Insurance system, we draw extensively on the experiences of multiple countries. Japan is one of those countries, though Japanese authorities demonstrate greater rigour. For instance, currently reasonable margin zones for branded products in Taiwan reach 15 percent; Japan maintains two to three percent thresholds within decades. Japan aggressively promotes patient empowerment requesting generic prescriptions, achieving utilisation targets significantly exceeding Taiwanâ??s current penetration.

Japan represents our primary role model, though within Asia, Korea merits examination. The Korean government vigorously protects the domestic pharmaceutical industry, particularly excelling in biosimilars where they substantially surpass Taiwanâ??s capabilities. Korean biosimilar manufacturers like Celltrion have achieved global prominence, for example.

How does TGPA collaborate with international partners, particularly the International Generic and Biosimilar Medicines Association?

IGBA maintains four working groups with monthly online meetings addressing regulation, biosimilars, elemental impurity studies, and international regulatory harmonisation. We joined IGBA to cultivate global perspectives for our members, facilitating export opportunities given Taiwanâ??s modest domestic market scale.

Alex Lin, owner of CHUNG MEI Pharmaceutical CO., and TGPA vice president is a member of IGBA, representing Taiwanâ??s pharmaceutical sector. He attends annual European meetings; though the last two years saw the suspension of physical conferences, although regular monthly meetings continue.

What proportion of the National Health Insurance Administrationâ??s pharmaceutical budget addresses generics, and how does this compare with foreign generic competition?

Total National Health Insurance Administration healthcare expenditure approaches NTD 950 billion. Pharmaceutical products represent approximately 25 percent â?? roughly NTD 230 billion. Generics constitute 25 percent of pharmaceutical spending, approximately NTD 56 billion, with foreign generics capturing nearly half this allocation.

Foreign generics â?? particularly from companies like Sandoz â?? achieve extraordinary competitiveness through global supply chain economies, enabling volumes substantially exceeding those achievable for Taiwan-only manufacturers. Their elevated production runs generate lower unit costs, creating pricing we cannot match.

We compete against globally-scaled manufacturers supplying Taiwan at prices local producers cannot economically achieve, given volume constraints. This represents critical discussions with authorities because all products, including OTC medications, require Taiwan bioequivalence studies. Conversely, foreign generics submit documentation without mandatory Taiwan bioequivalence trials, conducted in lower-cost jurisdictions, yet receive comparable reimbursement pricing. This competitive asymmetry substantially disadvantages domestic manufacturers.

Regarding export competitiveness, given Indian manufacturersâ?? aggressive pricing, are Taiwanese companies pursuing higher-value APIs or alternative differentiation strategies?

Indian APIs as well as finished products pricing proves extraordinarily challenging â?? impossibly low by Taiwan standards. We must develop higher-end APIs and finished product for competitive differentiation. However, biosimilars represent entirely different manufacturing paradigms from chemical pharmaceuticals. Taiwan maintains a separate biosimilar association under Mr Liu of EirGenix, Inc. leadership, though domestic biosimilar production remains limited with predominantly imported products. Even multinational companies like Amgen possessing biological and biosimilar

portfolios often decline to launch in Taiwan given pricing and regulatory constraints.

With the administrationâ??s NTD 20 billion NHIA budget allocation, what financial commitment can generic manufacturers anticipate?

The total allocation does not specifically earmark generic industry funding. However, the government now invests in advancing generic manufacturing technology and high-tech medicine production through a four-year plan from 2026, encouraging improvements in bioequivalence capabilities, manufacturing processes, and medicine quality. Generic companies demonstrate motivation by participating in government programmes to secure support resources, given constrained margins limiting independent investment.

When we joined PIC/S GMP certification over eleven years ago, every company invested substantially in facility upgrades. Current programmes provide welcome investment supplementation.

What message would you communicate to international audiences and the Taiwanese government authorities regarding the generic pharmaceutical industry?

Several structural trends will shape TGPAâ??s direction â?? notably stronger emphasis on supply chain resilience, evolving reimbursement frameworks, and increasingly stringent regulatory expectations related to quality and sustainability.

Taiwanâ??s generic industry is well-positioned to serve as a trusted, high-quality, and resilient supply partner. Manufacturers have participated in PIC/S GMP certification for over eleven years, consistently meeting international standards, and the government is supporting further capability upgrades through four-year modernisation programmes. We also welcome recent policy signals from the former Director of the National Health Insurance Administration â?? now Minister of Health and Welfare â?? to ease annual price reduction pressures, an important step toward restoring sustainable investment capacity.

However, API dependence remains a critical vulnerability. More than 70 percent of APIs are sourced from China and India. In the event of geopolitical disruption, domestic capacity would be insufficient to respond rapidly. This is not solely a defence issue â?? Taiwan is now a super-aged society, with over 20 percent of the population aged 65 and above, many reliant on continuous treatment for chronic conditions such as hypertension, diabetes, and cardiovascular disease. Medicine shortages would create immediate public health risks.

Taiwan has the technical capability â?? companies such as CCPC export more than 80 percent of their API production to the United States â?? yet domestic procurement economics often make local sourcing unviable given limited volumes.

Our message is straightforward: pharmaceutical resilience must be treated as a national priority and every effort needs to be put in to ensure uninterrupted access to essential medicines for an ageing population. This is fundamental for healthcare security, public health stability, and long-term societal sustainability.

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