ACCESS TO MEDICINE FOUNDATION

Tackling the diabetes care crisis in the Pacific: Insulin and medicine access

4 SEPTEMBER 2025

Access to insulin and other diabetes treatments is an urgent and dire priority in the Pacific – a region often left out of global health and commercial initiatives. This paper builds on research from the Access to Medicine Foundation, extensive research conducted in the region on the state of diabetes care, as well as stakeholder consultations, to offer practical approaches for optimising commercially viable routes to improve access and manage the growing need in Pacific island countries and areas (PICs).

The paper focuses on nine PICs that are covered by the 2024 Access to Medicine Index: Kiribati, Marshall Islands, Federated States of Micronesia, Papua New Guinea, Solomon Islands, Samoa, Tonga, Tuvalu and Vanuatu.

It is critical to note that the access challenges in PICs are complex and unique – and long-term solutions will require targeted action from governments in these countries and other stakeholders in the field of diabetes care to overcome systemic challenges that impact overall access and supply of medicines.¹

However, pharmaceutical companies have a critical opportunity to improve the availability and affordability of their lifesaving diabetes care medicines that are being commercially distributed in PICs, while assuring the quality of these medicines.

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Five key access issues faced in the region

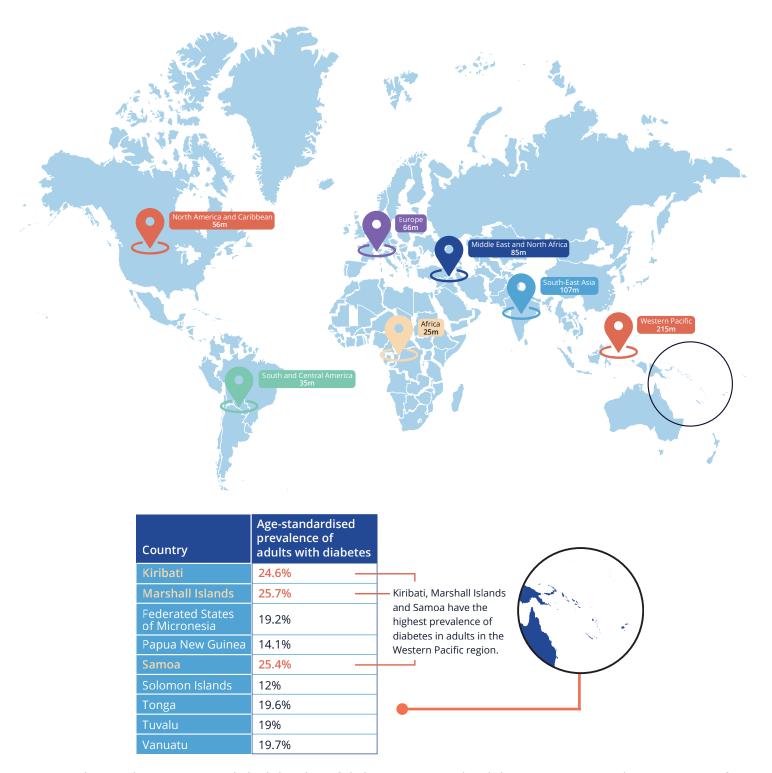
1 SMALL POPULATIONS

The medicine volumes required are relatively small, making the commercial viability of any single PIC market challenging. With smaller populations, there are also fewer resources to support local public health capacity. This encompasses not only healthcare professionals who can treat and support patients but also trained staff who can perform administrative and regulatory tasks, such as pharmacovigilance; in fact, none of the nine PICs currently have this in place.² Despite their small populations, these communities face some of the highest burdens of disease and are too often overlooked. Yet, they deserve the same quality of care and access to treatment as any larger population. In 2019, for example, 61 people living across the islands of Vanuatu had to have all, or part of, their lower limbs amputated due to complications from diabetes because they lacked adequate access to treatment.3

COUNTRY	ADULT POPULATION (20 – 79 YEARS) ⁴
Kiribati	74,300
Marshall Islands	25,100
Federated States of Micronesia	69,400
Papua New Guinea	* * * * * * * * * *
Samoa	119,000
Solomon Islands	383,200
Tonga	\$ \$ 59,300
Tuvalu	6,700
Vanuatu	173,400

7 HIGH PREVALENCE OF DIABETES

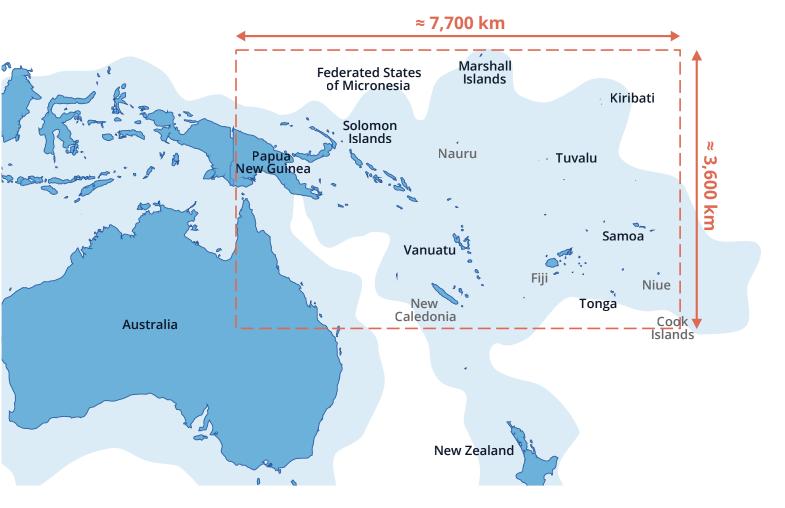
589 million adults (20-79 years) are living with type 1 and type 2 diabetes worldwide, with the Western Pacific Region accounting for over a third at 215 million⁴



PICs bear a disproportionately high burden of diabetes compared with larger countries in the Western Pacific Region. Kiribati, Marshall Islands and Samoa, for example, have the highest prevalence of diabetes in adults in the region, with the age-standardised prevalence of adults with diabetes over 24%. In comparison, the age-standardised prevalence in China is 13.8% and globally 10.5%.⁵

3. GEOGRAPHICAL REMOTENESS

Size and remote geographic location of Pacific island countries and areas present unique challenges



The remote geographic location of PICs hinders the accessibility of essential healthcare products, which need to be imported from larger neighbouring countries, like Australia, India or Malaysia. While air routes are used for certain small shipments or temperature-sensitive medicines, sea routes are predominantly used in this region.

4. SUPPLY AND QUALITY

Sea route shipments can take months to reach their destinations, thousands of kilometres away from the departure harbours, risking untimely delivery of medicines. Oftentimes, ships carrying medicines are not appropriately equipped with the stable storage that is required for certain medicines, such as insulin, which risks compliance with good distribution practice (GDP) standards.^{5,6} When GDP standards are not met, the stability and quality of medicines can be compromised through exposure to extreme temperatures, humidity and physical damage. And if the quality is substandard, the medicine may not be effective in controlling the condition or disease.

Once products reach harbours in PICs, last-mile delivery infrastructure constraints, such as the lack of adequate warehouse facilities for storing stability-sensitive medicines, further jeopardise quality and shelf life of these products – even if medicines have been produced under good manufacturing practice (GMP) standards.⁷

Climate change is expected to exacerbate these challenges by increasing the frequency and intensity of extreme weather events, as well as prolonged periods of heat and humidity, further threatening the integrity of medicine supply chains and storage in PICs.

5. PRODUCT CHOICE AND AVAILABILITY

Of the nine PICs, Papua New Guinea is the only country with a National Regulatory Authority (NRA) through which medicines can be filed for registration. Efforts are underway to progressively develop NRAs across PICs, and it will be important for companies to be prepared to directly engage with governments and regional authorities to explore filing for registration more fervently (see box-out below). Although filing for registration does not guarantee the availability of a product to all patients, it serves as a critical step for access to quality-assured medicines. To date, reports from the Access to Medicine Foundation^{8,9,10} and public sources demonstrate that no diabetes medicines, including lifesaving insulin, have been filed for registration in Papua New Guinea by the large research-based pharmaceutical companies or generic and biosimilar medicine manufacturers analysed.

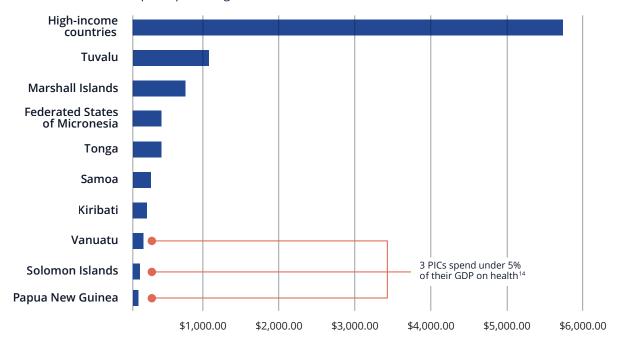
Nonetheless, short and intermediate-acting insulin as well as metformin are made commercially available in all nine countries through import waivers (see next section), but many of these medicines do not reflect the standard of diabetes care available in high-income

countries. Moreover, the costs of these medicines vary and stockouts are common. Insulin from multinational pharmaceutical companies is currently only available in limited quantities due to affordability issues, whereas metformin – used by type 2 diabetes patients – is largely available. Most medicines procured in PICs are distributed through public health systems, making diabetes treatments generally free or subsidised. However, some products still require out-of-pocket payments. Small, private health systems serve wealthier citizens and expatriates, sometimes supplementing public supply, though often at high personal cost.⁵

Many governments in PICs have limited financial resources for healthcare (see graph), making it difficult to secure enough quality-assured medicines to serve their populations' needs. Coupled with already existing supply chain delays that also contribute to stockouts, people living with diabetes in PICs are often left without optimal treatment options, which can lead to health complications – varying from mild to severe.

HEALTH EXPENDITURE PER CAPITA IN PICS VS HIGH-INCOME COUNTRIES

In 2022, PICs' health expenditure per capita spanned from USD 81.11 to 1084.67, averaging at USD 376 per capita, compared with to USD 5767.17 per capita in high-income countries.¹³



ADVANCING REGULATORY CAPACITY IN THE PACIFIC, INCLUDING QUALITY ASSURANCE

Some regional initiatives are already playing a valuable role in supporting regulatory developments. The Australian Therapeutic Goods Administration (TGA)'s Indo-Pacific Regulatory Strengthening Program, for example, aims to develop and strengthen the capability of NRAs across 22 countries in Southeast Asia and the Pacific to increase the availability of safe and effective medicines and medical devices through improved regulatory practice and regional collaboration. ¹⁵ TGA and the Australian Department of Foreign Affairs and Trade are also running the Pacific Medicines Testing Programme, which provides PICs access to Australian laboratory testing for therapeutic goods' quality assurance. ¹⁶

How are current actions addressing access issues?



Import waivers serve as a critical lifeline in supplying medicines

Most medicines that are available in PICs are purchased through national annual tenders, whereby each country's Ministry of Health procures medicines through import waivers and based on inclusion in the National Essential Medicines List (nEML), linked to national Standard Treatment Guidelines. Usually, a medicine cannot be procured for the public system if it is not on the nEML. Procurement happens at a national level and there is no pooling of demand in place. Similarly, shipments and supply are also not coordinated between the countries. Pharmaceutical wholesalers (see box-out alongside) participate in such tenders by putting in bids, with successful providers then shipping their medicines.

WHERE ARE MEDICINES BEING IMPORTED FROM?

Certain wholesalers are Australia-based, such as South Austral and Boucher and Muir, and typically source their products globally, with many manufactured in Bangladesh, China and India. These suppliers provide products that are both registered and not registered in Australia. Asia-based wholesalers are predominantly from India and Malaysia, for instance Baroko Sdn Bhd. They sell medicines that are mostly manufactured in Bangladesh, China, India, Indonesia and Malaysia. Smaller wholesalers based in Fiji, New Zealand and Papua New Guinea also operate in the region.



Regulatory reliance helps governments in PICs monitor the quality of medicines

While import waivers enable the commercial availability of diabetes medicines in the absence of registration, the mechanism prevents government authorities from conducting quality controls on medicines that are imported. To overcome this problem, many PICs use regulatory reliance, whereby a country utilises the assessment performed by another country's NRA or external authority for quality assurance. Currently, PICs mostly rely on the assessment decisions of regional mature regulatory authorities – notably Australia's TGA and New Zealand's MedSafe – and external authorities such as the WHO Prequalification of Medical Products (WHO PQ). While also a mature regulatory authority, the European Medicines Agency is utilised to a lesser extent for regulatory reliance by PICs. Other countries' NRAs – such as Fiji, Indonesia and Malaysia – are also less frequently used. The countries and authorities PICs rely on are typically listed in their legislation, but additional authorities that are not listed are sometimes used.



Affordability issues remain a challenge for expanding existing efforts

Affordability of medicines and health budgets remain a key problem in PICs. The Foundation's May 2025 Diabetes Care Programme report, Access to diabetes care for children and young people: Pharma companies' current actions and opportunities ahead (May 2025 report), highlights that any efforts to scale and sustain access to diabetes care will not be future proof if the issue of cost is not addressed. The report shows that some governments in low- and middle-income countries (LMICs) have started to take ownership of particular elements of diabetes care by, for example, partially or fully reimbursing certain diabetes care medicines. While governments in PICs are also doing this, financial constraints limit their ability to subsidise costs in a way that can ensure all patients living with diabetes can receive the care they need.⁵

Encouragingly, as identified in the <u>2024 Index</u>, pharmaceutical companies have developed business models tailored to specific markets, thereby improving affordability and health outcomes. Sanofi's Global Health Unit has pledged to supply diabetes care medicines to four of the nine PICs covered by the Foundation's research – Federated States of Micronesia, Papua New Guinea, Solomon Islands and Tuvalu. The Foundation's May 2025 report also found that Sanofi currently supplies its second brand insulin glargine (Impact SoloStar® pens) in Papua New Guinea through its Global Health Unit.

What actions are required now?

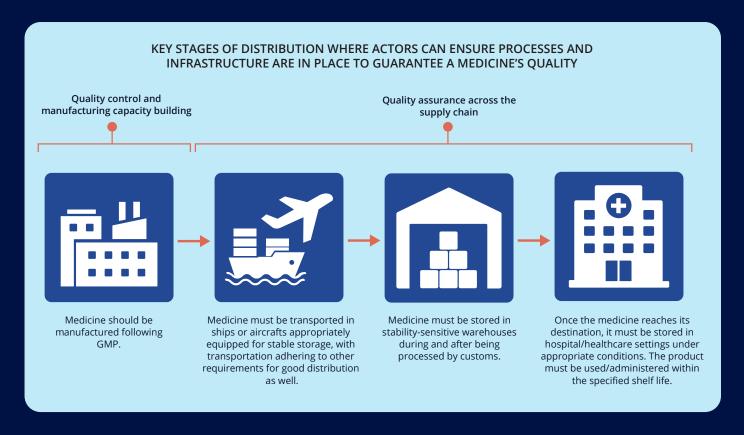
It's clear that access challenges faced in PICs are unique and complex. The limited demand in very remote and hard-to-reach destinations present commercial and logistical complexities for both companies and procuring governments. And while medicines are made commercially available, there are concerns around quality assurance; at the same time, when medicines are quality assured, they are oftentimes unaffordable.² Finally, the Foundation's May 2025 report highlights that any efforts to scale and sustain access to diabetes care medicines will not be future proof if the issue of cost is not addressed.

To solve these problems, pharmaceutical companies; governments in PICs, and in the region; international organisations; and philanthropic organisations in the field of diabetes care can focus on three main issues: supply, procurement and financing. In doing so, innovative partnerships present opportunities for efficiency and sustainability.



To assure the quality of the medicines supplied to and used by people living in PICs pharmaceutical companies and wholesalers must comply with stringent regulatory authorities' GMP and GDP standards, while the last-mile distribution should be designed to maintain the quality. Companies supplying PICs through third-party wholesale distributors should actively select and work with wholesale distributors who comply with GDP.¹⁷ All actors involved in procurement and distribution should be systematically audited and trained on quality assurance. They should establish clear local protocols for identifying and reporting substandard and falsified medicines while empowering healthcare providers and local wholesaler representatives to report issues, leveraging tools such as the WHO Global Surveillance and Monitoring System and WHO Rapid Alert System.

Finally, procurers and suppliers are encouraged to leverage innovations in supply to create efficiencies in the supply chain: pooled shipments may lead to efficiencies, while increasing flexibility to ensure regular and timely supply of lifesaving medicines.



PROCUREMENT

Companies should always file for registration of their products if the option is available, as is the case in Papua New Guinea. While the NRA's capacity may be limited and result in long processing times for dossiers, it is through the utilisation of this mechanism that inefficiencies, pain points and gaps can be identified and improved.

Public actors should develop and implement regulatory frameworks which appropriately incorporate regulatory reliance by trusted independent NRAs, adopting WHO's Good reliance practices recommendations. 18 PIC governments are also urged to pool their medicine procurement to increase their collective bargaining power and better coordination in the consistency of medicine supply and delivery.¹⁹ Governments can assess tender offerings not just on price, but also on quality assurance practices and delivery practices. A transparent and robust tender process builds confidence in the procurement process, attracting more competitive players to the market, and ensuring the right companies win tenders at the desired prices. Delivery infrastructure needs to be improved by investing in cold storage and other requirements for good distribution on ships, at customs, in the last-mile distribution and in health facilities. Echoing the call to action of other reports like the ACCISS, it appears that collaboration between PICS and regional actors, such as TGA and WHO, is more pressing than ever.



The recent shifts in global health funding signal the urgent need for more innovative and underutilised financing mechanisms for health coupled with complementary measures to improve the availability of diabetes care. Governments are encouraged to explore financing strategies which suit their national context, alongside the systematic development of their policies and health systems. Such strategies have been explored through additional research, including the WHO guideline on country pharmaceutical pricing policies.20 Meanwhile, the private sector can implement pricing strategies that account for the ability to pay of all local payers in these countries and ensure that these strategies are applicable across a wider spectrum of diabetes care medicines. Pharmaceutical companies providing essential diabetes medicines through business models tailored to specific markets need to move forward with commitments related to these models, ensuring their products reach the populations in PICs.

Through its <u>Access to Medicine Index</u>, <u>Diabetes Care</u> and <u>Generic & Biosimilar Medicines</u> Programmes, the Access to Medicine Foundation will continue to monitor access progress across the diabetes continuum of care, as well as other therapeutic areas covered by our work.

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