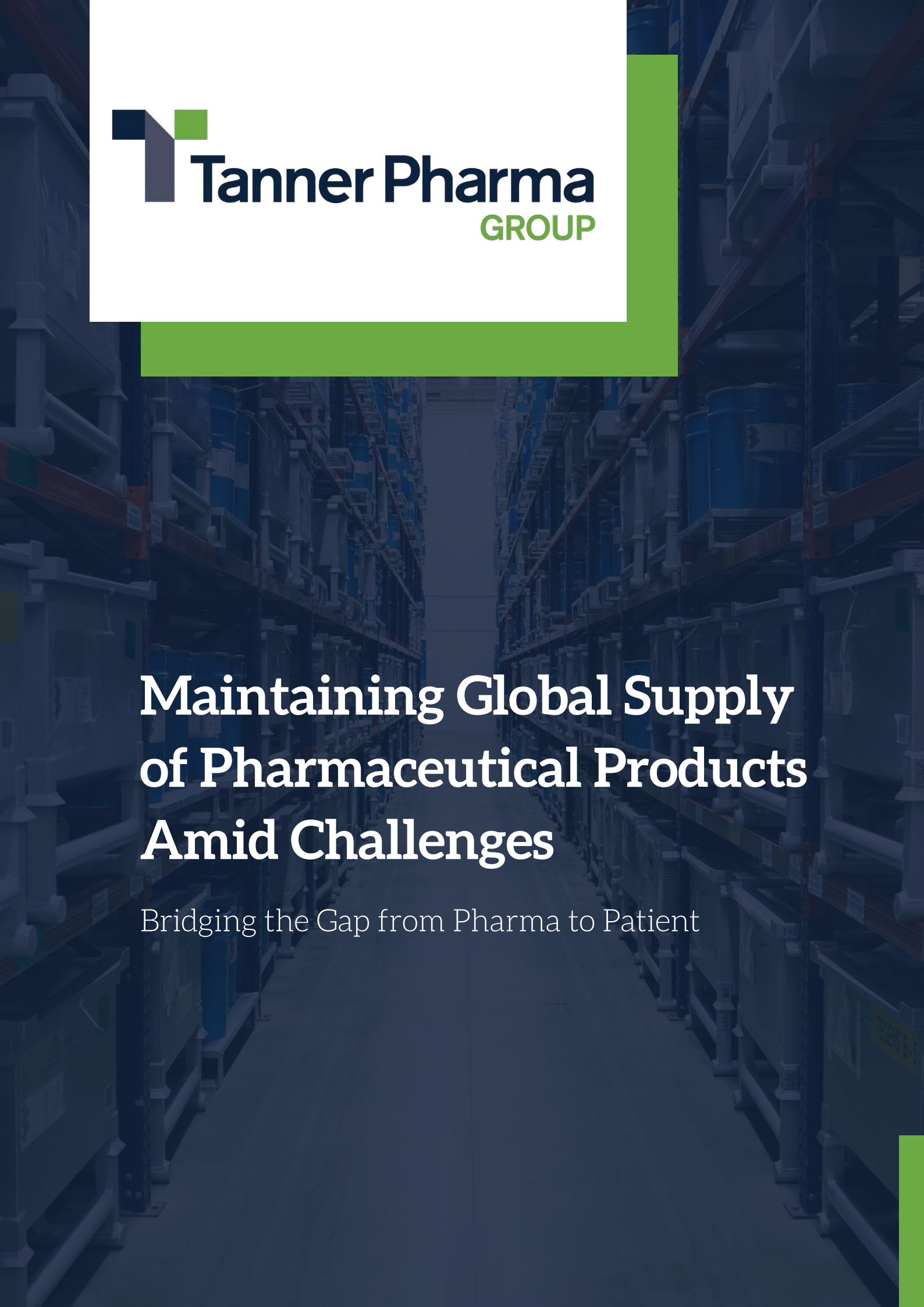

Tanner Pharma GROUP

Maintaining Global Supply of Pharmaceutical Products Amid Challenges

Bridging the Gap from Pharma to Patient

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Introduction

Managing supplies of medical products is a continuous process that requires effective forward-planning in procurement combined with the flexibility to adapt to meet changing demands in a crisis. The peak of the global pandemic of 2020 really highlighted the life-changing importance of preparation and response, and what can happen when supplies become depleted.

Being able to respond to medical needs in a crisis is vital. But those with the greatest levels of preparedness often cope the best. Preparedness is fundamental for supplies of medical products and being able to get ahead of the curve before a situation escalates is a considerable advantage. However, an immediate response involving medical products is not always during a crisis. Supplies of pharmaceutical products can run out for a range of other reasons, leaving patients without access to necessary treatments.

In this whitepaper, we examine some of the reasons behind the unavailability of medical products around the world and address various operations challenges and response protocols required to resolve these immediate demands, with expert commentary provided by Tanner Pharma Group.

Maintaining continuity amid drug shortages

Drug shortages are not a new phenomenon. In July 2018, US FDA Commissioner Scott Gottlieb called for pharma companies to increase investments in production capacity, highlighting how low-profit generic medicines were most likely to experience shortages as they can be expensive to manufacture.

"The low-profit margins, and the significant cost of manufacturing these complex drugs, have resulted in consolidation in the industry. The only way to produce these low-margin products profitably is to manufacture them at a tremendous scale. This has resulted in fewer and fewer manufacturers for certain key products," Gottlieb stated. Furthermore, Gottlieb added that these conditions had also resulted in an under-investment in manufacturing, notably in sterile injectable drugs.

"Unless drug makers are investing in their manufacturing facilities, it can create conditions that give rise to production stoppages in order to fix manufacturing problems," Gottlieb said.

But generics are not the only area of note when it comes to shortages. The range of shortages can include medicines, supplies, and even key active pharmaceutical ingredients (APIs). Multiple therapeutic areas can be affected by the shortage of just one treatment or ingredient, and these areas may be more common than you think.

Anesthesia has more dosage shortages than any other therapeutic area

Count of drug shortages by therapeutic area

Therapeutic area	Total drugs in shortage	Unique presentations in shortage
Analgesia/Addiction	7	116
Anesthesia	13	274
Anti-Infective	11	37
Cardiovascular	15	71
Endocrinology/Metabolism	14	82
Gastroenterology	20	174
Hematology	4	28
Neurology	7	76
Oncology	9	55
Opthalmology	8	43
Other	18	112
Pediatric	18	208
Psychiatry	9	42
Pulmonary/Allergy	6	37
Rheumatology	6	60
Total Parenteral Nutrition	7	45
Transplant	2	6
Urology	7	76

Note that some drugs are counted in multiple therapeutic areas. 'Total drugs in shortage' counts the number of unique generic names for all drugs in shortage. 'Unique presentations in shortage' counts the number of unique presentations/doses for all drugs in shortage.

Source: US Food and Drug Administration

According to recent GlobalData figures, the US FDA reported shortages of anesthesia drugs as the highest. This shortage has obvious consequences for patients in need of operations and may delay life-saving surgery. In second place is pediatrics, meaning that there is a lack of medical treatments for children. And if the US has seen issues with these shortages, then low and middle income countries around the world are almost certainly far worse off.

Drug shortages are a common occurrence but have seen a substantial uptick in recent years due to the numerous supply chain issues that have resulted from the global pandemic. Many global manufacturing facilities temporarily closed at the peak of Covid-19, with a scarcity of raw materials driven by supply chain disruptions. This has resulted in bottlenecks in production that are still being felt around the world.

Procuring medications across countries can be a tedious task, let alone transporting them from point A to point B when time is of the essence. Responding to these real-time needs requires a network of partners, combined with expert logistics and supply chain management.

“There could be many different reasons for shortages,” explains Vanessa Jijon Zaconet, Senior Director of Tanner. “For example, I’ve recently seen more products being sold across the marketplace. In these cases, it may take time to re-establish those distribution patterns, or they may need time to make a decision on where they’re going to sell the product and who is going to be allowed to buy it. Or they may be renegotiating pricing for manufacturing. This is just one example of a change that can lead to a country-specific or sometimes global shortage, and this is where we can help. We can help to mitigate those challenges.”

To manage some drug shortages or help prevent them from happening in the first place, governments will issue tenders for suppliers to build up supplies across areas where they are expected to see future demand, often years in advance.

These tenders are to ensure that stocks are available, rather than to address urgent patient needs, and are intended to decrease the lead time for patients. In some cases, hospitals decide not to reach out to just a few wholesalers for an unlicensed medicine but instead share tenders across online databases – such as NUPCO in Saudi Arabia – to enable a more competitive bidding process.

“We support a lot of tenders supplying hospitals, especially in larger Middle Eastern countries and the EU, with very large quantities of medicine aligned with what they expect they’ll need for the next three to five years,” shares Rilee Humphries, Senior Business Analyst at Tanner Pharma Group. “We supply orphan designation products and generics, branded or unbranded. Whatever the product, we will try to find a way to enable access.”

"Whatever the product, we will try to find a way to enable access."

Maintaining access continuity amid market withdrawals

For various commercial reasons, a pharmaceutical product may be withdrawn from a market, even when demand remains from physicians and patients. A manufacturer may discontinue the product intentionally from a particular region or county, or a merger or takeover may result in the new brand owner needing to re-register the medical product – meaning that it is taken off general sale until the process is complete.

Furthermore, production may shut down due to a lack of raw materials amid supply chain disruption. Market withdrawals are different from product recalls in that the medicine is not withdrawn due to safety issues. It is more a case of business decisions, leaving patients in certain regions lacking access when the product might still be available elsewhere.

The withdrawal of a drug from a market can create an urgent need for post-withdrawal access while planning is done for a safe transition to a new or alternative treatment. The shortage of a drug due to production problems, logistical issues, or a sudden increase in demand also poses risks of harmful impacts on patients. Depending on the product and the market, it may be possible to continue to provide post-withdrawal access to the market.

Having the ability to divert medicines temporarily from one country into another – using verified regulatory pathways – can provide a vital stopgap until the required registered products are available again. However, the issue can sometimes take years to resolve in some countries, meaning that long-term supplies are required for patients that may have limited treatment options. In some cases, a generic product or alternative form of the withdrawn product may be a suitable replacement.

“It could be that there are varying strength or dosage levels for a particular product,” shares Gaby Bedoya, BD Manager at Tanner. “For example, a medication that was previously taken from a vial is now available in tablet form and is more accessible in the market. Or maybe instead of an injection, the treatment can be taken through an inhaler. In these ways, we can procure different forms of the same product, or generic products, that can help meet a particular demand. Each country is different, so we also take into consideration compliance and logistics measures.”

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Meeting medical needs through Named Patient Programs

Often, the Tanner team receives requests from government agencies, hospitals, health authorities or NGOs. But in other instances where the need is often more extreme, contact may come from a residing physician or even the patient.

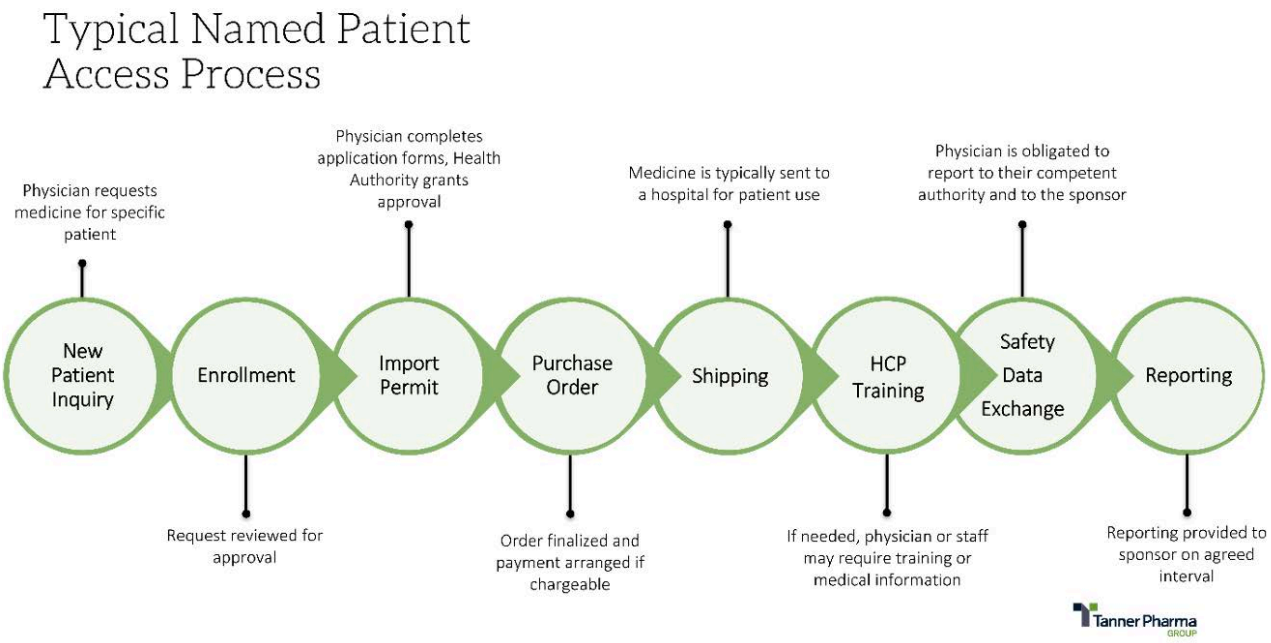
“Most of the time, patients or physicians that approach us directly are dealing with rare diseases, oncological conditions or other critical illnesses requiring immediate treatment. Many are requesting access to new therapeutic treatments or life-saving drugs that are not widely available. Usually, the requests are for branded products over generic products,” shares Maryori Alvarenga, EVP of TannerGAP.

In these cases, a Named Patient Program may be the best option. Named Patient Programs are a common practice in global access. These pathways involve enabling access to medicine on a patient-by-patient basis, based on requests from physicians on behalf of their patients. Alternatively, requests can come from the patient directly in certain circumstances. In both cases, the patients are unable to obtain a life-improving treatments within their home country for reasons that might include:

- The treatment is in the late stages of clinical trials or pending market approval
- The treatment is approved and has not yet been commercialized in the patient’s home country
- The treatment is approved and available in another country, but there are no plans for the product to be commercialized in the patient’s country
- There is a shortage of the treatment in the patient’s home country, but it is available elsewhere
- The treatment was discontinued in the patient’s home country but is accessible in another country

To enable supply, it must be confirmed that the patient meets the inclusion criteria, and facilitators must ensure there are established pathways in place in the patient's country. From there, necessary import permits must be obtained and approved by the local health authority. Only then is the product transported and supplied to the treating physician.

"Named Patient Programs are the primary mechanism we leverage to provide global access," Alvarenga explains. "We have different sourcing capabilities that can fit large-scale or niche needs and we have a lot of partners supporting a wide network of supply routes. If we can't get a product directly from the manufacturer, we go through their authorized distributor. We always manage to find the right supply route to source a product and then distribute it to the patient."



Meeting medical needs through Donation Programs

Another means for patients to access medical products is through donation programs, offering pharmaceutical companies a lower-cost alternative to bridge treatment for trial patients until a medicine is commercially available.

Donation programs are typically run in low and middle income countries where patients may not have the medical insurance or personal finances required to purchase essential medicines. Distance also plays a role for patients in these regions. Many have to walk or travel several miles to get to a medical facility – which can delay diagnoses, inhibit a necessary treatment series, and prevent access to much-needed products.

There is a growing interest in donating medicines in low and middle income countries where product demand is high. However, many companies that contemplate such socially driven initiatives are daunted by factors such as supply chain control and quality assurance concerns, inadequate understanding of local healthcare systems, and the requirement to partner with non-governmental organizations (NGOs) and ministries of health. Another barrier to treatment is the required insurance, financial means, or direct route to access.

Tanner began its involvement with donation programs by helping set up and manage the world's largest oncology medicine donation program in partnership with The Max Foundation, a global NGO committed to increasing global access to treatment, care and support for people living with cancer. The company has since worked with several pharmaceutical companies and NGOs on similar initiatives.

Since the Max Access Solutions programs began, Tanner has helped The Max Foundation deliver more than 25 million daily doses of life-saving medical products.

The procurement and distribution process can be complex but rewarding for those seeking to make an impact on global health equity. Tanner helps to make the complex clear, handling procurement and direct, temperature-controlled shipments, importation, and warehousing in local depots for onward distribution, and managing the pharmacy dispensations and home delivery in certain countries.

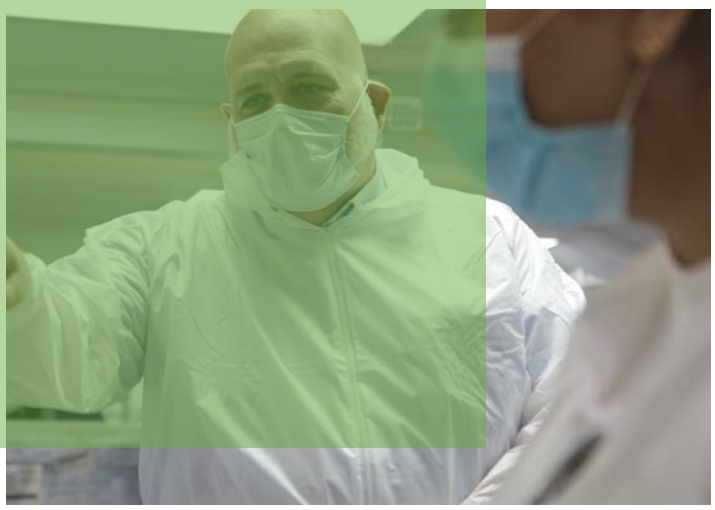
Managing unforeseen medical needs

There are many reasons why medicines are requested throughout the world, and different channels through which these demands can be met. Sometimes the demand is based on preparation for a future need, sometimes it's an ongoing need that requires oversight for many years. And on other occasions, it is responding to a shortage, a flaw in the supply chain, or a regional or global crisis. Medical product requests have always been present, but these demands substantially increase in intensity and urgency when political, environmental, and other unforeseen factors arise. A strong pharmaceutical services partner can help ensure response times are met and new challenges are managed.

Covid-19 Response

Responding quickly and adapting to changes at a moment's notice are essential elements when enabling product access. The Covid-19 pandemic that swept the globe is an extreme example of just how quickly demand for medical products can surge and how rapidly supplies can run out, even amongst the most established suppliers. The pandemic saw an intense uptick in the number of people seeking supplies of personal protective equipment, home test kits, hand sanitizer, oxygen tanks, and even ventilators.

And once supplies run out during a crisis, it becomes extremely difficult to replenish stocks. As was seen during the peak of Covid when alternative suppliers were urgently sought. The pressure to obtain products as quickly as possible meant that it was not always possible to carry out due diligence on suppliers. One common result was that large quantities of PPE were bought that ended up being unusable in many countries.



In the early days of the pandemic in 2020, Tanner began working alongside non-profit organizations to obtain and distribute supplies of medications and different PPE products. During this time, Tanner saw an opportunity to deliver wider support for the Covid-19 response.

“The main challenge was ‘pace’. Things were happening really quickly. There was a big spike in enquiries for huge quantities and trying to find reputable suppliers to meet this was incredibly challenging,” explains Jonathan Bracey, EVP of Corporate Development at Tanner Pharma Group.

The company already had the key strategies in place to support patient access to pharmaceuticals, but supplying PPE, test kits and other Covid-related medical supplies was new territory. Response time was crucial and having a strong network of global partners proved to be invaluable. Tanner leveraged its existing relationships with manufacturers and service providers, as well as its global supply chain, to build direct and effective distribution pathways to deliver necessary Covid-related medical supplies around the world.

Tanner's role in global access

Due to the ever-growing number of innovative medical treatments entering the market, requests for access are also increasing in low to high income countries globally. Demand for medication is never stable, and fluctuations in product access present new and unforeseen challenges every day. Managing these demands and mitigating unexpected challenges presents considerable difficulty, especially when a quick delivery is essential.

Tanner Pharma Group liaises with pharmaceutical companies, governments, NGOs, hospitals, and health authorities to meet the immediate medical needs of patients regardless of their geographical location. Whether this is addressing medicine market withdrawal, mitigating drug shortages, managing medicine supply on a Named Patient basis, or enabling product donation programs, the company's business model is built on responsiveness. And the company succeeds due to its agility and capacity to meet whatever demands are required.

"Our approach is very patient-centric," says Zaconet. "We are agnostic. It doesn't matter the volume or the cost of the medication, or the location of the patient. If we know there is a need, we find a way to enable access."

Tanner Pharma Group is a US-based pharma services company that provides specialized access solutions in international markets. Over more than two decades, Tanner has developed a portfolio of services driven by the determination to improve global access to medicines for patients.

Tanner offers GDP-compliant distribution of pharmaceutical products to and from countries on every populated continent. The company has a depot network of GDP-compliant facilities, with 2°-8°C and frozen capabilities, and employees working across three continents.

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