

## BEYOND THE PANDEMIC

# Solving Surprising Expanded Access Program Supply Chain Challenges

## THE CASE

A pharmaceutical company contracted Durbin's Expanded Access experts in 2018 for a unique product. The product was a first-in-class treatment for a neurological disorder which had no effective treatment, making it a strong candidate for an Expanded Access Program (EAP). There was a high unmet medical need for the product, so a successful implementation of the program was crucial.

## THE CHALLENGE

Our client's product was a difficult pharmaceutical to manage. The pharmaceutical had a controlled drug status and was the first of its kind to be included in an EAP. In addition, the drug needed to be transported under special conditions due to the product containing ethanol, a substance that is hazardous by air. The program encompassed five European countries, all with different customs requirements and variable drug classifications. Beyond maintaining compliance across the region, the controlled substance nature of the product required sophisticated security along the distribution chain.

This project presented challenges from the outset, but then in late 2019, the SARS-CoV-2 pandemic began. Some countries locked down and others changed regulations. Most importantly for supply chain, global transportation and shipping also slowed — at one point to 10% of its normal volume.

## DURBIN'S EXPANDED ACCESS PROGRAM SOLUTIONS

Durbin's secret to success sounds simple in theory, but it is difficult to execute in practice: we prepare proactively before issues arise. To meet our supply chain needs, Durbin maintains a global network of warehouses in the United Kingdom, United States and Ireland, and we find local partners in our other areas of operation, if required. With fully controlled, cold-chain-capable, state-of-the-art warehouses, we can stock product to ensure continuity of supply, even if a crisis interrupts the production process or product transportation.

Durbin won the contract by demonstrating our security and distribution expertise to the client during an on-site visit at one of our GDP-compliant facilities. In addition to these sites, we thoroughly vet our local partners to ensure they can stock product and perform last-mile deliveries.

Because the product was a novel drug, with no analogue in any previous EAP, Durbin had to navigate multiple regulatory issues. Durbin's team proactively contacted customs officials in

every country of operation for the EAP before we shipped a single dose. Given the controlled substance was also potentially explosive, these were extensive conversations with authorities, customs and border control to assure that the right paperwork was available. As the pandemic unfolded, our team contacted the appropriate individuals in customs to maintain continuity of supply, even as shipping was reduced, and regulations became stricter.

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SARS-CoV-2 was the most difficult issue to address, as it affected nearly every aspect of the program. When normal routes of transportation closed, we used our local stocks of supply while identifying creative solutions to move materials. Durbin advanced a multipronged approach, including both air and ground transportation. Commercial air traffic was not consistent enough to guarantee that product would reach patients on schedule. Instead, to meet our high standards for on-time delivery, Durbin chartered a plane to fly directly to high-volume locations. For ground travel, Durbin hired and ferried trucks to go from the manufacturing facility in the U.K. to mainland Europe.

As for the product, Durbin provided fully transparent tracking. We tracked every dose from the time the institution ordered it until it was given to a patient, in real time. At any given minute, Durbin and the EAP's stakeholders knew where each dose of the drug was, throughout the entire 500 days of the program.

### DURBIN EAP'S RESULTS

Throughout the duration of the EAP, Durbin delivered and maintained continuity of supply, regardless of regulatory hurdles or pandemic-induced delays. Our expert logistics and warehousing capabilities gave us the flexibility to adjust in real time to every challenge.

The program exceeded our sponsor's expectations. The EAP ran over 500 days across five countries, including France, Germany, Italy and the U.K. In total, we supplied 513 institutions with ~47,000 bottles of the drug, which treated 3,143 patients who did not have access to another effective treatment.

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Durbin leveraged relationships from previous programs to benefit this drug program. We had previously worked with many of the institutions involved in the EAP, due to our history of experience in the therapeutic area, which facilitated easier communication and troubleshooting during the program. Combined with our detailed tracking and project management, we set up over 1,250 physicians for success. The physicians knew where the doses for each patient were along the chain, so patients were only called into the institution when the product was available, saving everyone time.

While the program was ongoing, the EMA approved the product for commercial use. This transition from non-commercial to commercial product is often difficult, but there were no

problems at any institutions involved because Durbin contacted them proactively to know the exact date of the transition and how to navigate the requisite paperwork. This was a hugely complicated program management task, which Durbin executed successfully. In fact, the real-world data (RWD) collected from the EAP was so compelling that the sponsor was able to use it as a submission for reimbursement.

Because of Durbin's proven excellence in providing 360° full support to their EAP in such a challenging environment, the sponsor has awarded additional EAP projects to Durbin, in other therapeutic areas.

### CONCLUSION

Durbin was able to meet or exceed sponsor and stakeholder expectations in delivery of a difficult new drug product through one of the most challenging supply chain disruptions in recent history. Our proactive approach to maintain continuity of supply allowed us to adapt to problems before they depleted our stocks. If you want an experienced global EAP service provider, Durbin can deliver.

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### ABOUT DURBIN EAP

Durbin is a specialist medical supplier distributing unlicensed pharmaceuticals to 160 different countries. Durbin works in partnership with global pharmaceutical and biotech companies to provide Expanded Access Programs, including Named Patient Supply and Cohort Programs.

The company has 25 years' experience designing and implementing EAPs from concept and specialises in developing robust and compliant voluntary data collection initiatives, which run seamlessly alongside the programs they manage.

Those initiatives help partners capture real-world insights from outside the clinical trial environment that can then have a variety of potential uses, ranging from regulatory and payor negotiations to informing future study design.

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