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Addressing the Challenges of Comparator Drug Sourcing for Clinical Trials

Accessing comparator drugs for use in clinical trials can be difficult, and pharma companies and clinical research organizations (CROs) conducting clinical trials are not always prepared to overcome the intrinsic challenges to guarantee the needed supply. Establishing a comparator sourcing strategy during protocol development – that includes a partnership with an organization that focuses on providing comparator sourcing solutions – is essential to minimize the time, cost and hurdles involved in procuring comparator drugs for clinical trials.

Comparator Drug Challenges

In many cases, pharmaceutical manufacturers place restrictions on the sourcing of their products for use as comparators, including limitations on quantity, long approval timelines and requirements for additional disclosures. In fact, most pharmaceutical companies impose restrictions on providing their products for international trials. For sourcing biologics, there are additional challenges, because most biologics manufacturers do not have any internal policies and procedures in place to supply their products for clinical trials. This lack of internal guidance leads to significant confusion and delays. Products that fall under Risk Evaluation and Mitigation Strategies (REMS) – and those that are unavailable through the typical supply chain – can also be difficult to access.

Even when drug makers support the use of their products as comparators, it can still take a very long time

to receive approval for comparator requests. In addition, most studies require that all comparator materials be sourced from a single manufacturing lot. Procuring large quantities from a single lot is challenging, owing to a variety of factors.

Complicating the situation is the fact that many clinical trial managers seek assistance for comparator sourcing very late in the project rather than during the establishment of the study protocol. Because the cost of comparator drugs is often higher than expected, some managers seek the lowest-cost supplier and, unfortunately in many cases, they are faced with late or failed deliveries, which adversely impacts project timelines.

Finding the Right Sourcing Partner

Finding the right partner for comparator drug sourcing is essential to overcoming these challenges. An effective sourcing partner has long-standing relationships with large, multinational manufacturers and independent pharmaceutical companies worldwide, allowing for cost-effective sourcing for even challenging products.

As importantly, a comparator sourcing partner must have excellent quality and compliance management systems in place and be well versed in risk mitigation. A commitment to the delivery of high-quality material on time and at the right locations is also critical.

Sourcing Solutions, Not Just Drug Products

The best comparator sourcing partners provide not just comparator drug prod-

ucts, but tailored solutions designed to meet the specifications of each customer. They help their clients optimize clinical trial supply with a combination of global reach and local presence.

A global network of leading drug manufacturers and major wholesalers and an experienced team of sourcing specialists can enable a supplier to provide cost-effective access to many products, in large quantity, even for the most difficult-to-source items. Fast delivery is possible through access to a global warehousing and distribution network.

Meet Globyz Pharma

Globyz Pharma is dedicated to the sourcing and supply of commercial medicines/comparators for clinical trials studies across all therapeutic areas. We offer global sourcing, GMP-compliant storage, packaging and labeling, global distribution and cold-chain supply solutions. With access to comparators that are hard to find and under restricted distribution, Globyz is a global comparator sourcing partner delivering the right medications to global clinical sites in a fast, safe and cost-effective manner.

We focus on providing integrated customized solutions with the highest standard of quality and service. Globyz Pharma's vision is to provide tailored innovative solutions for clinical trial material sourcing and to become the most reliable partner for high-quality clinical trial materials and services. Whether you are seeking comparator sourcing alone – or a comprehensive solution that includes packaging, warehousing, distribution and regulatory support – we can customize a sourcing program, especially for your needs.

With years of experience, Globyz Pharma possesses strong expertise in managing the regulatory, logistics and supply chain challenges of sourcing, storing and distributing comparators for global clinical trials. **P**