

Options for comparator drug procurement



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Deciding what kind of supplier to procure comparator drug products from is a sensible place to start and four primary options are available for sponsors to choose from.



Option 1 – direct from marketing authorisation holder

Due to commercial sensitivities, biopharmaceutical companies occasionally agree to supply peer or partner organisations with their commercial drug product for use within comparative studies. However, commercial sensitivity may restrict a manufacturer's willingness to supply its commercialised drug to its competition.

Subsequently, this method may prove overly challenging for comparative trial sponsors. Yet, if this barrier can be overcome with robust supply agreements, sponsor may leverage the benefits of a direct sourcing approach which can include lower costs, long expiration dates, and shorter lead time availability.

Option 2 – specialist sourcing organisations

Treating comparator drugs as commodities, these suppliers have expertise in sourcing the drugs sponsors need to fulfil study requirements but, due to small size, restrictions in the supply reach can sometimes lack the capabilities expected by research organisations.

Option 3 – pharmaceutical wholesalers

Wholesalers represent a value for money proposition for sponsors with robust, in-house supply chain management expertise and resources. They will reliably source comparator products but rarely offer the guidance and support most sponsors need in order to effectively balance risk and cost, manage expiry dating issues, complete necessary documentation for product movement and assure resupply to patients.

Option 4 – clinical supply chain experts (eg: Almac)

Sponsors can choose to partner with an established clinical supply chain management vendor, with the ability to identify suitable comparator, along with the optimal source to procure them, and provide expert guidance relating to available options, market limitations and lead times. These organisations can leverage their relationships with MA holder's, wholesalers and specialist supply companies to define and deliver best-fit sourcing strategies that assure supply to patients, while minimising the risk of delays, shortages, product waste and spiralling costs.

Additional benefits of working with a clinical supply chain expert is that they may also be able to provide analytical support and QP services for comparator drugs.