Ask RxSource

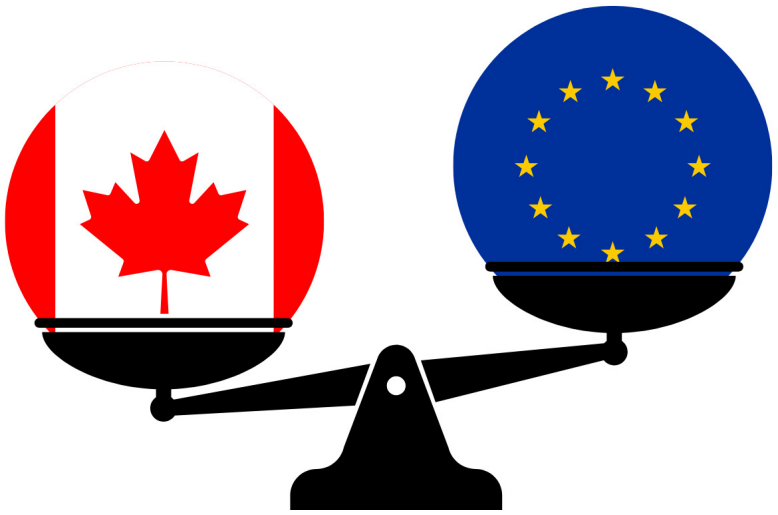
Is Canada a good alternative market for comparator sourcing? Why?

RX SOURCE Clinical Services

At RxSource, we routinely source comparators and co-medications from the US and EU markets. However, as is widely reported, drug pricing is significantly higher in the US than in many other markets. If a company is performing a trial in the US, is it mandatory to use US-sourced product? What alternative markets can be used?

We have seen increasing demand for Canadian products for use in global and US-only trials. Canadian product is generally about 50% of the US price for the same medicine. The decision to source product in Canada is not always based on pricing. For example, we recently sourced high volumes of drug for a client's US trial. As a result of drug shortages in the US, the manufacturer of a particular product was refusing requests to supply the product for clinical trial use, either directly or through wholesalers. Our client needed the product for an impending clinical trial, and asked if we could source from an alternative market. Our research revealed that no such embargo was in place in Canada. We were also able to obtain an equivalency statement from the manufacturer that demonstrated the US and Canadian drug product were identical. The end result was that the client was able to commence their clinical trial as planned…with the added bonus of saving $millions on commercial drug costs.

The EU also offers competitive pricing, and is often used as a central source of commercial product for all trial sites, including those in the US. If drug is being repackaged/relabelled for clinical trial use. However, we have seen commercial product provided as-is, or with minimal labelling, to clinical sites for open-label trials. If medication was sourced in a non-English speaking EU country, is this acceptable to the site, regulators or, most importantly, patients in the US – or is additional work required to translate patient leaflets, or to over-label packs? English is an official language in Canada, so sourcing from the Canadian market can reduce the level of additional work required.



A final consideration when planning to source from an alternative market, is to ensure Regulatory Authorities are comfortable with this. While we are not directly involved in these discussions (it is usually the Sponsor or CRO), we have seen clients successfully implement alternative sourcing strategies by having these discussions with Regulators as early as possible in the protocol approval process. Discussions should cover:

- Why this is being done? For example, if the US is part of a global trial and most patients will be outside of the US, this can help justify use of ex-US product. Low availability of product in the US, or a risk that the volume needed by the trial could impact on the overall market availability of the product, may also persuade Regulators to accept your proposal. We suspect that 'to save money' will carry much weight.

- Can you demonstrate equivalency? For example, can you obtain equivalency statements from the manufacturer to verify that the product you intend to use is the same as US product? Can you provide a certificate of analysis for the product to demonstrate it meets manufacturer's specifications and/or pedigree documentation to demonstrate that it is not a counterfeit?

We have focused on the use of Canadian products in the US, where they may address availability and cost challenges. In other regions, such as the EU where Canada's price advantage is reduced, Canadian product can still help companies solve availability issues. Canada has a Comprehensive Economic Trade Agreement (CETA) with the EU, which allows for easier importation and release of Canadian products into the EU vs. the USA equivalent product.

Looking at alternative markets can offer up some attractive sourcing options. Not only can it provide a more stable, untapped supply of drugs, but it can reduce procurement costs. As with everything else our advice is to always consider alternative options – but start planning for these as early as possible!

Ian Ball, Associate Director - Procurement

17 years+ Industry Experience

3 years+ with RxSource

ian.ball@rxsource.com