Cognitive dissonance is a psychology or behavioural theory to explain how people can hold and act on contradictory views at the same time. It is a very familiar concept in consumer research, and a good reason for including observation as part of a programme of consumer immersion. By doing this, it is possible to understand whether what a person says they do contradicts how they live their life.

A classic example is people who smoke (their behaviour), who know that smoking causes cancer (the cognition), yet carry on smoking. Over time, people’s attitude may change, but in the present, they have an inner drive to avoid disharmony through justifying their contradictory beliefs. For example, one way the dissonance can be managed is by reducing the importance of one of the cognitions. Some smokers justify their activity through wanting to smoke and have pleasure today, rather than worry about the future. The short-term benefit (smoking) is more important than the long-term outcome (risk of cancer).

The development of biosimilars has produced a form of cognitive dissonance amongst payers, physicians and patient groups. They want to evaluate biosimilars in terms of safety and efficacy, but the development focus for a biosimilar is to establish similarity to the originator. It means that the way these products are evaluated is complex and, at times, confusing.

Biosimilars are very different to generics. They have a high level of molecular complexity and can be very sensitive to changes in the manufacturing process. With small molecules it is possible to prove that they are the ‘same’ as the originator, with biologics, while the protein sequence may be identical, the cell line and culture conditions mean that the mature protein may be difference. Generics are structurally identical to the originator, biosimilars are clinically identical.

For originator products, payers and physicians balance the risks and the benefits of the clinical data. How will the drug significantly improve the outcomes for the patient compared to what is already available, and what are the safety risks? With the current level of economic scrutiny of new medicines, it is critical to show clear differentiation for a product versus current standard of care, or the appropriate comparator.

The assessment of biosimilars requires a very different mindset. They require a fundamental shift in how products are developed and evaluated, as the focus is on similarity rather than efficacy and safety. Evaluating a biosimilar requires establishing the bioequivalence between the follow-on product and the reference biologic and where there are any clinically meaningful differences (now a negative element, not a positive one).

This is a difficult mind-set shift for all stakeholders. There is dissonance in having to focus on the similarity rather than the efficacy and safety.

Understanding that dissonance will exist in the evaluation of a biosimilar gives good direction for how we should assess reaction to the product and potential uptake. A manufacturer may have to accept that it will be necessary to undertake education on the category in general. Patient groups in particular express concerns about the safety of biosimilars and the automatic substitution that could come with them. They aren’t (yet) looking at the similarity, but the safety.

Biosimilars are complex, unpredictable molecules. Developing them is totally different to manufacturing a generic. However, if they are subject to the same clinical trial rigor as the originator, where is the economic benefit?

Maybe this is the heart of the issue. Price is the driving factor, with biologics looking to come in with around a 30% reduction in price from the originator. Is this enough of a motivation to reduce the importance of one of the cognitions?

Ultimately, it is critical for business intelligence to apply this same mind set change when considering new types of product. Evaluating the potential for a biosimilar should not be conducted in the same way as that for an originator or generic. Otherwise the cognitive dissonance trap is set.