Review of: "Interchangeability of biosimilars: A study of expert views and visions regarding the science and substitution"

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After reading the paper, I concluded that it made no sense to referee this paper as a standard scientific paper. Rather than commenting the validation of the methodology of the data collection and their interpretation, I want to bring up some aspects which may help to solve the regulatory confusion about the clinical use of biosimilars. This is a (good) opinion paper discussing the evolving opinion about the interchangeability of biosimilars and positions regarding substitution based on interviews with regulators and experts from the pharmaceutical industry.

The main finding of the paper is the paradoxical situation in which experts who are hesitant about complete interchangeability of biosimilars cannot indicate what kind of clinical evidence would be needed to consider a biosimilar interchangeable.

To understand this paradox a number of aspects are important:

1. There is scientific definition of a biosimilar and it can be seen as a regulatory construction. A biopharmaceutical is a biosimilar, if the regulators say so.
2. The lack of a scientific definition (which will also be very difficult to formulate and to get consensus on) makes it also impossible to describe a biosimilar in qualitative and quantitative terms. So a biopharmaceutical is either a biosimilar or not. (Although some manufacturers claim they produce better biosimilars than their competitors.
3. Because it is a regulatory construction, science will never be able to make a distinction between interchangeable and non-interchangeable biosimilars.

As a final remark: for this paper only regulators and company experts were interviewed and no clinicians. I have the impression that most clinicians already have concluded that biosimilars are completely interchangeable and switch them freely.