

A patient-centred paradigm for the biosimilars market

This article provides important insights into the use and application of complex biologicals, particularly biosimilars, in health delivery systems. One aspect of care that has been traditionally ignored by providers as well as the private sector is the patient experience. Although much has been said about 'patient-centeredness', what this means generally is lip service to minor changes and form, rather than a substantive focus on what, how, and when patients receive 'treatment', not just a drug.

Importantly, patient safety principles have more recently indicated the essential nature of including the patient in systems of care to both improve communications and reduce harm associated with potential medical errors. For biosimilars, these principles have heightened importance, as biosimilar molecules and forms have not been cooperatively designed and hence may be associated with higher level of potential adverse reactions, particularly unwanted immunogenicity. Hence, developing a pathway of care that addresses the needs of patients–from the outset of care when these drugs are considered, through education on use, through feedback on (potentially adverse) reactions, through feedback on systems that allow for patient needs to be communicated to the delivery structure–must be the new normal. Biosimilars have tremendous potential to improve quality and quality of life as well as access to cutting edge therapeutics, but their increased risks associated with immunogenicity heighten the need to focus on the pathways of care relevant to the patient, rather than simply creating a drug, or dispensing a drug, or injecting a drug.

Hopefully, this work is disseminated widely to the public sector, the private sector, and providers as well as patients so that a coordinated 'system' of care employing these molecules becomes standard. Patients must be empowered to be part of the system, not merely a 'market', or a 'constituency', or a passive participant in treatment. Only in this way can the maximum benefits from these molecular entities be inured to all patients, wherever they are, whichever culture they are in, and however they receive their therapies. As the world becomes a smaller place, these global health concerns will only grow, and the need to focus on true partnerships between all stakeholders engaged in delivery will be needed to address the needs of patients now and for generations to come.

Professor Bryan A Liang, San Diego Center for Patient Safety, UC San Diego, USA

Generics and Biosimilars Initiative Journal (GaBI Journal). 2012;1(1):17-21. doi: 10.5639/gabij.2012.0101.006

South Korean guidelines for biosimilars

It is crucial for the drug price control authority to take more responsibility to protect interests of patients. At least to fix prices in case of an adverse situation where a pharma and generics collaborate to create a monopoly.

http://gabi-journal.net/news/south-korean-guidelines-for-biosimilars

Indian Government issues first compulsory licence

The practices of the two biggest Delhi patent law firms are absolutely no indicator of the right position on the law.

Section 79 of the Patents Act, 1970, lays down only the procedural requirements, not the substantive law requirements which will still be guided by the Evidence Act, 1872. One can use a particular patent document as evidence through an affidavit but then the admissibility or that particular patent document can be objected to by both the opposite side and the patent office on the grounds that it has not been authenticated as per Section 65B of the Evidence Act.

http://gabi-journal.net/news/indian-government-issues-first-compulsory-licence