Global Standards for Biosimilars

Bella Smith

Abstract

Introduction

As biopharmaceutical technology becomes more widely used in the treatment of diseases such as rheumatology, cancer and other chronic diseases, professionals in the pharmaceutical industry predict that half of the newly approved drugs will soon come from biomedicine, which has also boosted The pharmaceutical industry has a huge interest in developing biosimilars. The possibility of selling currently sold biopharmaceuticals that have passed the patent protection period is becoming more and more attractive to many biopharmaceutical companies, especially in the next few years, many biopharmaceuticals will lose patent protection.

Biogenerics are new copies of the original biological products that have been approved by the law. Unlike generic generic drugs, the US Food and Drug Administration (FDA) defines common generic drugs as: they contain similar bioequivalence within the same or acceptable range as small-molecule products. Pharmaceuticals have the same dosage, efficacy, safety, efficacy, suitability, and management methods. Biosimilars are macromolecules made from biological organisms and their products, usually macromolecules with high complexity. In addition, the differences between the two include that chemical generics are often very stable, while biosimilars are very sensitive to changes in production processes.

Patients and doctors may be reluctant to switch to original brand drugs and switch to biosimilars, or they need sufficient evidence to show that they have the same efficacy and safety. As a biosimilar manufacturer, it has no access to the cell bank, molecular cloning and the exact same fermentation and purification process used in the development of the original drug, and the production process cannot be reproduced. In order to ensure full confidence in biosimilars, regulations are needed to reduce users' concerns about the different performance of biosimilars compared to the original drug. Unlike chemical generics, each biosimilar requires clinical trials because even small differences in product impurities, decomposition materials, or molecular makeup can cause serious health problems in patients.

Current regulations in Europe and America

The drug approval regulations that the European Medicines Agency (EMEA) has begun to implement specifically distinguish between chemical generics and biosimilars. The European Medicines Agency recognizes that the approval procedures for chemical generics are not suitable for biosimilars because of the complexity of biological and biotech derivatives. In 2006, the European Medicines Agency was the first in the world to issue regulations for the review of biosimilars, providing a 10-year data protection period for generic drugs and biologics for biosimilars. The European Medicines Agency is also aware of the need to reduce risks for patients and the need to protect their safety, so the European Medicines Agency has a relevant legal framework to require extensive testing before approval of biosimilar products.

The EU's technical guidelines recognize the differences between biosimilars and existing biologics in

raw materials and manufacturing processes, and subtle differences may affect the safety and effectiveness of biosimilars treatments. Therefore, the European Medicines Agency is aware that biosimilars may cause immunogenic problems that are not fully detectable in clinical trials and that are not available in the original drug. And the European Medicines Agency also believes that this safety and efficacy issue may also occur in products that look completely similar. Therefore, the European Medicines Agency adopts a one-by-one review method to require pre-clinical comparison tests between generic and original drugs through appropriate methods. Although the requirements for biosimilars in Europe are much higher than those of chemical imitations, they offer a more convenient drug approval channel. The publicly available technical guide provides guidance for the development of many products.

In March 2010, US President Barack Obama signed the Affordable Health Care for America Act5. The bill provides a means of approval for biosimilar drugs. According to the Act, biosimilars are products that are highly similar to the referenced patented drugs. Although there are subtle differences in the inactive ingredients between the two, the biosimilars and reference drugs are safe, purity and efficacy. There are no meaningful differences in clinical aspects. The Act stipulates that the expected results of any biosimilar for the immunogenicity assessment, pharmacokinetics, and pharmacodynamic clinical trials of all patients participating in clinical trials should be consistent with the clinical trial results of their reference drugs.

The new regulations also give the original pharmaceutical pharmaceutical companies 12 years of market access protection, during which other companies can not make similar biosimilars, while other traditional drugs have a corresponding protection period of at least 5 years. In addition, the legislation establishes a legal framework that allows biosimilar manufacturers to obtain approval from the US Food and Drug Administration for their listing. Compared to the 2008 biologics legislation, the Congressional Budget Office is expected to save about $25 billion in spending over the next 10 years, as the legislation will drive a significant decline in the price of biological products.

However, when it comes to this 12-year period of protection for the original drug, the World Congress of Generics Conference held in London in February 2010 concluded that the extended protection period would seriously hinder the development of biosimilars. The bill has been strongly opposed by generic manufacturers, and some politicians believe that the patent protection period should be shortened so that the development of biosimilars can be basically financially viable. At the same time, however, the original drug manufacturer insisted that the 12-year protection period is important to stimulate/encourage innovation and to compensate for the huge investment it makes in developing new biopharmaceuticals.

The world's first approved biosimilar with significant safety and efficacy was approved by the European Commission in 2006. Despite the fact that biosimilars exist in Europe, the prospect of biosimilars in the US market depends on the implementation of regulations passed by Congress. Observers are eager to see how the first biosimilars approved in the US passed regulations in practice and how the US Food and Drug Administration will test the new biosimilar regulations.

Global regulatory outlook

Pharmaceutical companies around the world are trying to make progress in the field of biosimilars. In particular, some countries that have approved the listing of biosimilars based on their existing regulatory requirements (eg India), as well as some countries and regions that have established special approval regulations for biosimilars (eg Europe, Canada, USA) , Japan, South Korea, China).

A few years after Sandoz, a Swiss subsidiary of Novartis, entered the biosimilars market, industry insiders found that legislators are becoming familiar with the field (more than 13 biosimilars have been approved in Europe). In the next few years, it is expected that a number of generic companies will try to enter the Western biosimilar market. Indian pharmaceutical companies Ranbaxy, Dr Reddy's Laboratories and Biocon are working hard to obtain European approval for their biosimilar products and will subsequently apply for US approval. Despite these ambitious plans, there are still considerable barriers to entry for these pharmaceutical companies, such as regulations, patent litigation, and market access.

Biosimilars such as biosimilar monoclonal antibodies are a rapidly growing field in the pharmaceutical industry. US market research firm Decision Resources found that almost a quarter of the 100 most important drugs in 2007 were biological products, and 13 of them had sales of more than $2 billion worldwide. The appeal to biosimilar bacteriophage companies is undoubtedly that many of these drugs will lose patent protection in the next 5 to 10 years.

With the development of industry, the development of globalization will be of great significance for pharmaceutical companies to maintain competitiveness and financial health. This is also the only viable way to increase the effectiveness of biopharmaceuticals worldwide and to make them affordable and accessible. The European Generic Drugs Association (EGA) recommends that in order to achieve this goal, a scientific approach should be adopted to achieve globalization, so that regulatory approvals can be obtained in major markets.

Citation: Bella Smith Global Standards for Biosimilars. **protocols.io**
dx.doi.org/10.17504/protocols.io.rv3d68n
Published: 23 Jul 2018

Protocol