Biotech in China

The biosimilars pathway is critical for China's biotechnology industry – and this is evident in the investment the government is making in the manufacture of biotech products

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Biotechnology can help society solve old problems in new ways. Through the science of using living cells and the discovery of new molecules, biotech innovation has the potential to address our most urgent needs: fighting disease; feeding the hungry; and improving the environment. Countries all over the world are recognising the importance of biotechnology for their economies, the health and well-being of their citizens, their food supply, and their ability to generate clean energy. Nearly every major country has adopted programmes to generate a homegrown biotechnology sector and the well-paying jobs it supports.

China, in particular, has made growing the biotechnology industry one of its top national priorities. With more than one-fifth of the world's population, it is an important market for biotech products and plays a key role in biotech product development and manufacturing. Recognising the country's great potential for sustained growth and global leadership in the industry, the Chinese government is sparing no expense to put companies and innovation on the map. The region is expected to issue its first set of regulatory standards for companies developing biosimilars, or follow-on biologics. The country is moving its pharmaceutical regulations closer to international standards, with the aim of speeding up drug registration.

Biosimilars Blueprint

Biotechnology figures prominently in China's 12th Five-Year Plan. Largely considered their blueprint for strategic economic growth and investment in the country from 2010 to 2015, the plan highlights seven emerging industries that could transform China's economy and drive growth. As one of these seven pillars, the biotech industry will receive a large slice of the $1.7 trillion pie the Chinese government has allotted for the plan's implementation. China's Minister of Health has pledged the country will spend an additional $11.8 billion to advance biotech innovation from 2015 to 2020, as the country looks forward to its 13th Five-Year Plan.

Among the current priorities, China's State Food and Drug Administration (SFDA) has begun to draft guidelines for biosimilar drugs, calling on scientists and entrepreneurs to actively participate in the process. The biological products division has established four working teams to encompass policy, quality control, and pre-clinical and clinical research. An additional consultation team comprising scientists, researchers and entrepreneurs from overseas and domestic companies is also in formation.

In contrast to biosimilars, SFDA has implemented regulations supporting speedier regulatory review of 'new drugs for special approval' since January 2009. This special approval status streamlines communications and reviews with SFDA during the application process and may also reduce the data submission requirements. Often called the 'green channel' - this pathway covers: new treatments for AIDS, cancers and rare diseases; new drugs targeting diseases without effective treatment; drugs and biological products that have not been approved worldwide; and biological extracts new to the Chinese market.

Approval Process

In all countries, special regulations are required for the approval of biotech products similar to others that have already been approved. In the case of traditional products, manufacturers are able to produce a generic product that is bioequivalent to an

innovator product. Thus, regulators may rely on safety and efficacy data of the innovator product to approve the generic version. In the case of biologics, however, a generic manufacturer cannot replicate precisely the cellular or molecular processes that the original manufacturer used to produce the innovator product. As a result, the generic 'biosimilar' product will vary from the innovator product to some extent. Regulators, therefore, cannot rely exclusively on the data supplied by an innovative biologic to approve a biosimilar. Some governments have developed a biosimilar pathway that takes into account the difference between the products and allows biosimilars to be approved.

With China striving to modernise their regulatory system, there are basic guiding principles all countries need to consider to ensure that drugs developed and approved are acceptable in all global markets. In order to ensure that new biotechnology products continue to reach patients and physicians, any statutory pathway for the approval of biosimilars must protect patient safety and preserve incentives to innovate. There are clear and key principles that governments must keep in mind when developing a regulatory pathway for biosimiliars.

Perhaps most importantly, patients should not have to accept greater risks or uncertainties in using a biosimilar, rather than an innovator's product. Therefore, it is important to ensure the approval of biosimilars is based on the same rigorous standards of safety, purity and potency applied to the approval of the pioneer biotechnology products, and to recognise that clinical trial evidence and data are fundamental for evaluating and demonstrating the safety and effectiveness of a biosmilar, and must be conducted on a product-by-product basis. Approval agencies should avoid specific constraints on the scientific conclusions in evaluating the similarity or comparability of biosimilars. Once a product is approved, reviewers should assign a non-proprietary name readily distinguishable from that of the innovator's version. Furthermore, adequate post-market evaluation of biosimilar products is also critical.

Secondly, reviewers must recognise the scientific differences between drugs and biologics. Large molecule biologics are much more complex than small molecule chemical drugs. Methods used to show that one chemical drug is the same as another are different from and insufficient for biologics, and small product or manufacturing differences in biologics can result in significant safety differences in and/or effectiveness.

Thirdly, the physician and patient should make treatment decisions. Small molecule generic drugs can be designated as therapeutically equivalent and may be dispensed interchangeably with innovator products without physician knowledge. In contrast, the current state of science is not sufficient to establish interchangeability for complex follow-on biologics. Accordingly, governments should ensure that patients are not given biosimilars unless expressly prescribed by a physician.

The Next Stage

Next, incentives for innovation should be preserved through research, development and the manufacture of new innovative therapies and cures, as well as new indications for such products. These include substantial non-patent data exclusivity, during which time biosimilar manufacturers could not rely on the government's prior approval of pioneer biologics to support approval of their own products. It is important to respect intellectual property and other legal rights. Biosimilar products should not be approved until after all statutory protections, including data exclusivity and patent protections, are no longer available for the approved pioneer product. Adequate notice and process rights will ensure that any patent challenge involving the biosimilar product will be litigated prior to marketing approval of the product, in order to protect the innovator's intellectual property rights and avoid confusion in the medical, patient and payer communities. Transparent statutory and regulatory processes for manufacturers of innovator products should provide full and fair opportunities to engage government and other stakeholders in a meaningful public process.

Review and approval of new therapies should be prioritised by regulating agencies. Any applications for approval of biosimilars will raise novel and complex questions of science and law, requiring substantial time and additional resources to ensure a thorough regulatory review for safety, purity and potency. In order to avoid slowing down the government's review and approval of new therapies, many for currently untreatable and serious diseases, it is imperative that the workload associated with these new applications does not harm the government's ability to efficiently review new drugs and biologics, and that new treatments continue to have the highest review priority.

With the Chinese government's high ambitions to become a driver of innovation, the country has great potential to make significant contributions to growing the global industry and providing tremendous benefits to society.

About the author

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