Ensuring Access to Biological Drugs for the Developing World

BRICS Working Group for the Research of Competition Issues in Pharmaceutical Markets

by the BRICS Competition Law and Policy Centre, BioPharma International Exhibition&Conference, Institute of Chemical Technology and FAS Russia

March 6th, 2024

Venue: Bombay Convention & Exhibition Centre, Mumbai
Time: 9.30 AM

Biologics are a class of medications derived from living cells by bioprocessing typically through genetic manipulations. The examples include monoclonal antibodies, growth factors, hormones, gene, and cellular therapies all of which are extremely effective in managing several types of diseases and disorders such as cancer, inflammatory diseases etc. which are otherwise difficult to treat.

Due to the inherent structural complexities of these drugs, development and manufacturing for these drugs is extremely difficult and expensive, resulting into exorbitantly priced drugs for the patients. Moreover, biologics are typically covered by several process patents over and above the product patent and therefore the lesser priced generic versions of these biological drugs – biosimilars – face several challenges to make it to the market and reach the patients. These challenges can include regulatory hurdles due to lack of uniformity across different countries and unadapted patent laws that limit the access to these often life-saving drugs, especially for patients from developing countries. This is further aggravated by the fact that patents on biologics are normally owned by incumbent manufacturers that have been infamous for engaging in anticompetitive practices to secure their market position.

Thus, ensuring access to biologics and biosimilars to guarantee the right to health of people in the developing world, a concerted and resolute effort by countries is urgently needed. As growing and dynamic economies, the BRICS countries have enough potential to adapt uniform legislative and regulatory practices while facilitating manufacturing and R&D cooperation to enable access to biosimilars for patients within and outside the BRICS geographies. The biosimilars market is growing and can compete efficiently with the incumbent manufacturers of biologic drugs. Therefore, by bringing together their industrial leverage and expertise and empowering their respective regulatory frameworks, the BRICS countries are capable of building their independent market for biosimilar drugs that will be driven by fairness and universal access to healthcare.

As part of a research project that brings together policy researchers and pharmaceutical experts from several developing countries, the BRICS Competition Law and Policy Centre has initiated this workshop as a forum for academics, regulators, and industry representatives from the BRICS states. The goal of the workshop is to discuss avenues for improving access to biologics and biosimilars in the BRICS with an emphasis on collaboration and concerted action by all the BRICS members.

The questions to be discussed include the following:

- What is the current state of R&D and manufacturing of biologics in your country? Is market access for biosimilars ensured and what are the obstacles?
- How can regulatory frameworks in the BRICS countries be aligned? What is the role of patent law and competition law to ease market access of biosimilars in the BRICS?
- Is there a potential for an institutionalized, joint platform of the BRICS countries that would act as an enabler of joint R&D and manufacturing effort?

Moderator:

- Alexey Ivanov, Director, BRICS Competition Law and Policy Centre
- Samir Kulkarni, Professor, Institute of Chemical Technology, Mumbai, India

Greetings:

- Suresh Prabhu, Founding Chancellor, Rishihood University
- Hemant Shetty, CEO, CHEMTECH & Jasubhai Media Pvt Ltd

Keynote:

- Dr. Rajesh Gokhale, Secretary; Department of Biotechnology, Government of India (TBC)
- Timofey Nizhegorodtsev, Deputy Head of FAS Russia
- Prof. Abhay Karandikar, Secretary; Department of Science and Technology, Government of India (TBC)
- Prof. Aniruddha Pandit, Vice Chancellor, Institute of Chemical Technology (TBC)

Speakers (Discussion Participants):

- Mrudula Bele, Associate Professor, MVP Samaj's College Of Pharmacy
- Andrey Ivaschenko, Head of Board of Directors, Chemrar Group of Companies (virtual)

- Roman Ivanov, Vice Rector, Sirius University of Science and Technology
- Dr. Vishal Warke, Director; Himedia Laboratories
- Mahesh Balghat, Managing Director and Group Chief Executive Officer; Veeda Clinical Research Limited
- Huang Yuwei, Official, Antimonopoly Enforcement Department I, State Administration of Market Regulation of the People's Republic of China (virtual)
- Sh. Sukesh Mishra, Director (Law), Competition Commission Of India (virtual)
- Ujjwal Kumar, Associate Director & Deputy Head, CUTS International
- Vitor Henrique Pinto Ido, Programme Officer, Health, Intellectual Property and Biodiversity Programme, South Centre (virtual)