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Re: Comments on the Rules for the Implementation of Regulations on Management of Human Genetic Resources (Draft for Comments)

Dear Sir or Madam,

The Biotechnology Innovation Organization (BIO) welcomes the opportunity to provide comments on the proposed Rules for the Implementation of Regulations on Management of Human Genetic Resources (HGR). BIO acknowledges the efforts of the Division of Science and Technology for Social Development of the Ministry of Science and Technology (MOST) to further develop rules on the management of HGR to further harmonize existing rules with the recently enacted Biosecurity Law.

BIO recognizes the collective aims of MOST and the National People's Congress to present an HGR and Biosecurity legal framework that aims to protect national security, respond to biological threats, and safeguard Chinese citizens' lives and health. Notwithstanding these otherwise legitimate policy objectives, BIO is concerned that certain provisions in the current draft HGR Rules would unnecessarily restrict research and development efforts in the life sciences in both China and abroad, impeding the development of scientific advancements for the benefit of Chinese citizens and mankind. After the State Council Order No. 717, "Regulation on the Management of Human Genetic Resources" was promulgated in July 2019, the HGR regulation, under its interim regulatory framework, has posed unnecessary and onerous barriers for the global biopharmaceutical industry, resulting in delays in global clinical trials and R&D initiatives. In our assessment, the current Rules do little to provide greater clarity and ameliorate the challenges to global R&D endeavours.

Noting the desire to promote biosecurity and innovation in biotechnology, BIO would like to respectfully share with you our concerns with specific provisions of the proposed Rules, particularly in Chapter IV (Sections III and IV) dealing with International Cooperation, that in our view would discourage, rather than enhance, mutually beneficial global scientific collaborations. For instance, provisions around the sharing of data with partners abroad and concerning the ownership of IP rights run counter to the desired intent of the Biosecurity Law and that, if implemented, may have a

significant adverse impact on the global biotechnology sector's efforts to develop breakthrough innovative therapies to promote global public health and wellbeing.

*About BIO*

BIO is a not-for-profit trade association with a membership of more than 1,000 biotechnology companies and organizations from the United States as well as 30 other countries. BIO's member companies research and develop innovative health care, agricultural, industrial, and environmental biotechnology products.

The innovations in our members' pipelines, across the spectrum of the life sciences, have the potential to profoundly improve quality of life around the world. Medicine will be revolutionized by better diagnostics and cures for diseases. Food security will be improved by the acceptance and deployment of climate-resilient technologies in plants, animals, food, and feedstuffs. Our ability to reduce emissions to tackle climate change will be made possible by fostering biobased manufacturing and the use of low-carbon fuels.

Over 90% of BIO's members are small and medium sized enterprises (SMEs), many of whom are still pre-commercial. In the biopharmaceutical space, these small, pre-commercial companies drive the innovation pipeline, accounting for over 70% of the early-stage clinical developments. In recent years, due to the progress of China's drug policy reform, these innovative SME firms are increasingly considering the China market as an early target for global collaboration and expansion.

*Scope of Human Genetic Resources – Article 2*

Human genetic resources are broadly defined in the Biosecurity Law to apply to physical specimens, i.e. tissue samples, as well as data, such as genomic information. Article 2 of the current proposed Rules do not further clarify or refine the broad definition of Human Genetic Resources. Additional clarity on the scope of the definition of Human Genetic Resources are encouraged and BIO recommends efforts are made to limit the scope to gene sequencing data and keep this as narrow a definition as possible to prevent subjecting a wide range of scientifically relevant data generated from a clinical setting do not needlessly fall under these Rules.

*Transparency and Greater Stakeholder Engagement in Procedures for Obtaining Licenses for International Collaborations and the Export of Human Genetic Resources to Foreign Entities – Chapter IV, Sections III-IV*

Chapter IV, Sections III and IV, of the proposed Rules address, respectively, the procedures for obtaining appropriate licenses for international research collaborations and the export of human

genetic resources abroad. BIO urges that, for the purposes of biomedical R&D, including early-stage R&D, clinical studies, as well as post-commercialization pharmacovigilance, that human genetic resources should be allowed to be shared with foreign collaborators in a timely and efficient manner. Otherwise, the utility of the derived data and the ability to drive global research and development projects would be significantly undermined. The restrictions on obtaining and using human genomic resources should be limited in scope to enable research and development while still addressing intended biosecurity public policy objectives.

The process to obtain licenses, as envisioned in these Sections of the proposed Rules, must be transparent, fair, and expeditious. BIO welcomes further clarity on the mechanisms that will ensure more robust stakeholder engagement in these licensing processes. Some BIO members have reported significant delays to obtain approvals under the current regulatory framework and this has resulted in a challenging environment for global biotech innovation, particularly for our SME firms, slowing down and inhibiting the advancement of certain research programs.

*Intellectual Property, Data Sharing and Benefit Sharing Considerations – Articles 15 and 16*

Article 59 of China's Biosecurity Law enacted in April 2021 requires that any international scientific research collaboration using China's HGR shall ensure the Chinese partnering entity's substantive participation in the entire course of research and sharing of resulting rights and benefits according to the law. The proposed HGR Rules, in Article 15 (also Article 24 of the HGR Regulations), reiterates Article 59 of the Biosecurity Law and further requires that all records and data information shall be fully accessible, and backup provided, to the Chinese partner.

The proposed HGR Rules not only require full substantive participation in the entire course of research and data localization in Article 15 but also contemplate joint IP and data ownership – irrespective of actual contributions of the parties involved or the contractual commitments agreed upon between the local Chinese and international research institution.

For instance, Article 16 of the proposed Rules (like Article 24 of the HGR Regulations) clearly provides for joint patent filings and eventual co-ownership of patent rights. This suggests that under the proposed Rules a pharmaceutical company would be required to share patent ownership with hospitals running clinical trials, regardless of the party's actual contribution (or lack thereof) to the subject invention. Moreover, the mandatory sharing of patent rights under Article 16 runs contrary to China's Patent Law, where patent rights follow inventorship and can be subject to party's agreement. For example, Article 8 of the Patent Law states that for an invention made through the joint work of two or more entities or individuals, or made by an entity or individual upon the authorization of another entity or individual, the right to apply for a patent shall, *unless it is otherwise agreed upon*, remain

with the entity or individual which made the invention or with the entities or individuals which jointly made the invention. After the application is approved, the entity (or entities) or individual(s) that filed the application shall be the patentee. Article 14 further states that where the co-owners of the right to apply for a patent or the co-owners of the patent right have agreed on the exercise of the right, such agreement shall prevail.

The requirement for participation and sharing of interests by Chinese institutions may implicate a foreign institution's ability to maintain control of intellectual property assets that pre-exist a collaboration with Chinese partners, for example, in instances where genetic data of diverse geographic (Chinese and non-Chinese) origin must be pooled and aggregated as part of the research. Know-how and insights derived by foreign researchers analyzing data should not be required to be shared with a Chinese entity, unless this data and information sharing arrangement has been freely and willingly agreed upon by both partnering institutions. The coercive sharing of data and relevant interests over the course of the research and development is an unreasonable obligation and one that may not be compliant with China's existing international obligations. Instead, BIO urges for a reasonable approach to intellectual property rights borne out of these partnerships, an approach where intellectual property rights can be negotiated freely amongst parties in a collaborative, rather than coercive manner. Striking the proper balance here will incentivize and promote more harmonious and constructive scientific collaborations with the innovative biotechnology community around the world.

When taken together, these provisions on IP, data sharing, and benefit sharing do not accelerate global R&D efforts but, rather, create challenges to cultivate long-term collaborative scientific relationships and deter global partnerships.

Furthermore, the IP sharing requirement of the proposed HGR Rules, and Article 59 of the Biosecurity Law by extension, is inconsistent with the spirit of the U.S.-China Phase One Agreement. For instance, Chapter 2 of the Agreement dealing with Technology Transfer provides in Article 2.1 that "Natural or legal persons ("persons") of a Party shall have effective access to and be able to operate openly and freely in the jurisdiction of the other Party without any force or pressure from the other Party to transfer their technology to persons of the other Party." Biopharmaceutical firms conducting clinical trials in China therefore should not be subject to sharing in IP or "relevant interests" beyond what is necessary for the successful, efficient, and safe running of the clinical study.

*Unique SME Considerations*

Navigating this legal and regulatory framework to establish meaningful and long-lasting scientific collaborations is a complex and time sensitive endeavour for BIO members, particularly for our

innovative, pre-commercial companies. In addition to the HGR Rules' impact on BIO's membership and their interest in research and development efforts in China, the Rules could set an international precedent and lead to unintended consequence if other countries follow suit and put in place similar policies. This will further weaken the ability of the global innovative biotech community, including the ability of innovative Chinese entities, to partner internationally. Obstacles to scientific collaboration between global and Chinese researchers would undermine scientific advancement and, more importantly, does a disservice to global public health and the development of treatments to benefit all of mankind.

*Conclusion*

The current Covid-19 pandemic underscores the importance of enhancing global scientific cooperation and BIO and its members welcome China to play a constructive role in this global collaborative process. The efficient flow of scientific resources and information related to Covid-19 is, for example, critical to develop innovative medical products. In the spirit of reinforcing greater international cooperation, BIO encourages the MOST to reform, rather than reaffirm, the current regulatory mechanism overseeing human genetic resource materials and to ensure scientific resource material, including biological samples and data, is able to be obtained and shared in a timely and efficient manner with researchers globally. This commitment will help us in the face of any future public health crises and help the innovative biotech sector continue innovating promising new treatments to improve public health outcomes.

Global society depends on life science innovation, especially the critical collaborations with Chinese scientists and partners, to solve some of the most pressing concerns facing humanity. Strengthening scientific cooperation between China and the global biotech community should be a priority and can be incentivized appropriately without impinging on national security or biosecurity considerations. Unfortunately, in our estimation, the relevant provisions in the current draft HGR Rules do not achieve this goal.

We are hopeful that through a collaborative dialogue with our Organization, we can work together to shape a policy framework for data that will enrich scientific partnerships with the global scientific community and China, enabling the next generation of data-driven, life sciences innovations to be developed for the benefit of mankind, while preserving legitimate national security and biosecurity interests. Our Organization stands ready to serve as a resource and share our collective perspectives.

BIO is grateful for the opportunity to submit comments for consideration of the Division of Science and Technology for Social Development of the Ministry of Science and Technology. Please contact Justin Pine, at jpine@bio.org if you have any further questions.