

**Meeting of the States Parties to the Convention
on the Prohibition of the Development,
Production and Stockpiling of Bacteriological
(Biological) and Toxin Weapons and on Their
Destruction**

9 July 2019

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2019 Meeting

Geneva, 3-6 December 2019

**Meeting of Experts on Cooperation and Assistance,
with a Particular Focus on Strengthening Cooperation
and Assistance under Article X**

Geneva, 29-30 July 2019

Item 6 of the provisional agenda

Identification of challenges and obstacles to developing international cooperation, assistance and exchange in the biological sciences and technology, including equipment and material, for peaceful purposes to their full potential, and possible ways and means of overcoming these

**Facilitating the fullest possible exchange of science and
technology under Article X**

Submitted by the United States of America

Summary

Innovations in biotechnology and global health are increasingly made in the private sector. States Parties can avail themselves of the benefits that cooperation with private industry offers by creating environments in which these industries can thrive. Such environments include sound intellectual property rights based in law; a skilled workforce; investment in educational infrastructure; support for research in universities and research institutes; laws and policies on commercial activities and competition that are robust, transparent, and encourage foreign investment; and regulatory infrastructure and frameworks that promote trade and foreign direct investment.

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1. The United States places great importance on cooperation and assistance under Article X “to facilitate the fullest possible exchange of equipment, materials, and scientific and technological information for the use of biological agents and toxins for peaceful purposes.” This commitment is illustrated by activities described in the reports submitted by the United States on its implementation of Article X.¹

2. Other visible indicators of the U.S. commitment to the full implementation of Article X include the variety of international exchange programs for scientific research funded by various U.S. Government departments and organizations, such as the National Institutes of Health, the Department of Agriculture, and the Food and Drug Administration. Such international collaboration enhances the quality of research and allows scientists to work with people and institutions that complement their work, wherever they are located. Though the breadth and scope of U.S. contributions and assistance relevant to Article X preclude a comprehensive listing of every program, this paper presents additional areas where the U.S. shares expertise applicable to technology transfer, in this case, related to attracting partnerships with the private sector and to foreign direct investment.

I. Additional Avenues for International Cooperation Under Article X

3. Not all U.S. activities and programs that promote exchange, cooperation, and assistance are undertaken by the United States Government. They are also undertaken by individuals, industry, foundations, universities, and other non-governmental organizations. Partnerships with these entities are essential to facilitate the fullest possible exchange of scientific and technological information to enhance a State Party’s biotechnology capacity. The private sector plays an important role in international cooperation, as noted in the Final Document of the 8th Review Conference.²

4. From academic institutes, to industrial and government research centers, to independent laboratories, progress in life science research is increasingly driven by innovation and open access to the insights and materials needed to advance specific initiatives. In 2015, U.S. industry, academia, and government funding contributed \$495 billion to scientific and engineering research and development (R&D) efforts, out of \$1.9 trillion worldwide, or 26 percent.³ The largest performing sector of this research and development was the business sector, which conducted 72 percent of the U.S. total, and 18.9 percent of the global total. In comparison, only \$54.3 billion, or 11 percent, of research and development in the U.S. is performed by federally funded research centers and agency intramural laboratories. This demonstrates the extent to which scientific R&D occurs outside of the government sector and the potential benefits from engagement with these other communities.⁴

5. Engagement with the private sector is an important avenue for the transfer of technology and information. The biopharmaceutical industry is one of the most research-intensive industries in the United States, and its significant investments in R&D result in major contributions to the economy. U.S. companies invested 55.8 billion dollars in domestic

¹ BWC/MSP/2018/MX.1/WP.7; BWC/CONF.VIII/INF.4; BWC/MSP/2014/MX/INF.5

² BWC/CONF.VIII/4.

³ National Science Board, Science and Engineering Indicators 2018 Report, <https://www.nsf.gov/statistics/2018/nsb20181/data/sources>, Figure 4-5 and Table 4-3.

⁴ National Science Board, Science and Engineering Indicators 2018 Report, Table 4-3.

R&D in 2017, and 15.6 billion internationally.⁵ They have invested more than half a trillion dollars in R&D over the past decade.⁶ Foreign direct investment by private corporations can be a major driver for technology transfer, as well as a powerful engine of economic growth. While corporations may have a variety of reasons for engaging in foreign direct investment, their decisions will usually take into account the profitability and future success of any investment. Therefore, the policy and regulatory decisions of States Parties exert tremendous influence on these investment decisions and can support and encourage opportunities for engagement with the private sector.

II. Practical Measures to Encourage Partnerships with the Private Sector

6. While the United States notes the importance of “facilitating the fullest possible exchange of equipment, materials, and scientific and technological information for the use of biological agents and toxins for peaceful purposes,” consistent with Article X, such exchanges must not be imposed by one country upon another, nor by a country’s government upon its private sector; rather, these exchanges should be voluntary and on mutually agreed terms. In particular, States Parties’ governments should not compel the private sector to transfer its technology. In order to maximize the benefits to all involved, such exchange requires cooperation from both parties. Therefore, States Parties can and should explore steps they can take to encourage the private sector to voluntarily share its advances and to carry out research in their countries by building an environment conducive to such exchanges, including encouraging foreign direct investment. Thus far, however, the practical measures that States Parties can take to encourage investment and technology transfer have gone largely unaddressed in discussions of Article X. This paper seeks to identify steps that States Parties can take to create an environment conducive to further cooperation, and highlights some existing U.S. programs that can assist them to do so.

A. Create innovation-friendly political environments with sound intellectual property rights based in law and regulation

7. Recognized, effective, and predictable intellectual property (IP) protections provide an important incentive for mutually beneficial investments in innovation, and facilitate technology transfer around the world. They enable innovative ideas and technologies to become marketable and profitable, and allow collaboration while protecting the rights of the original inventor. The quality of its national intellectual property law and practice is a factor determining the extent to which a country is able to participate in international innovation networks and the attendant knowledge transfer.⁷ Industry may be reluctant to engage in certain countries if weak IP regimes require them to incur additional costs to protect against unlicensed imitation of their products, for example. Strengthening IP regulations and harmonizing rights and protections with international norms can diminish costs to industry, which often leads to increased foreign direct investment in, and technology transfer to, host countries. The U.S. Chamber of Commerce’s International IP Index finds that economies with robust IP protection are twice as likely to provide environments that are conducive for

⁵ 2018 PhRMA Annual Membership Survey, <https://www.phrma.org/report/2018-phrma-annual-membership-survey>

⁶ *Ibid*

⁷ United Nations Economic Commission for Europe, Innovation and Intellectual Property Good Practices and Policy Recommendations, 2013

biotechnology innovation and that they experience on average 12 times more clinical research on biologic therapies.⁸

8. One way the United States is assisting countries in strengthening their IP protections is through the U.S. Patent and Trademark Office's Global Intellectual Property Academy (GIPA). The academy provides training in the intellectual property disciplines of patents, trademarks, copyrights and IP regulations enforcement to officials from intellectual property offices in their respective governments. The program aims to help countries around the world bolster their IP programs and services by sharing best practices and therefore improving patent quality around the world. In fiscal year 2018, GIPA provided 92 training programs to almost 4,000 foreign government officials from 83 countries on a variety of intellectual property topics.

B. Develop a skilled workforce, invest in educational infrastructure, and support research in universities and research institutes

9. Education policies designed to develop and sustain a skilled workforce can play a direct role in attracting foreign direct investment. A continuing supply of educated and technically proficient workers who can receive, sustain, and translate the knowledge and technology from private-sector investment is a critical element in supporting a biotechnology industry. Supporting national and academic research institutes, ensuring access to high-quality science education at every grade level from primary to university and postgraduate programs, and providing incentives to attract private sector investment in education are all policy initiatives that States Parties can take to increase foreign direct investment and create jobs in this knowledge-intensive sector.

10. One example of U.S. support for international exchange programs and scientific research is the Partnerships for Enhanced Engagement in Research (PEER) program. Funded by the U.S. Agency for International Development's (USAID) Global Development Lab, and implemented by the U.S. National Academies of Sciences, Engineering, and Medicine, PEER funds scientists and engineers in developing countries who partner with U.S. government-funded researchers. The PEER program directly supports scientists in these countries through institutional research awards of up to \$300,000. The goal of PEER is to help build capacity among local scientists and research institutions, strengthen research partnerships world-wide, and better translate data and evidence into policy. Since its launch in 2011, PEER has awarded nearly \$50 million to more than 250 projects in 50 countries.⁹

11. U.S. academic institutions also promote exchange, cooperation, and assistance by training students from other countries. In the 2017 academic year, more than 800,000 international undergraduate and graduate students were enrolled in U.S. colleges and universities. Fifty percent of those students were studying science, technology, engineering and mathematics subjects, and 8 percent, or nearly 67,000, were studying physical or life sciences.¹⁰ In 2016, temporary visa holders received 3,362 doctoral degrees in the life sciences, 26.7 percent of the total awarded in those fields, or 6 percent of the total doctorates awarded in the U.S.¹¹ Contributing to this information exchange, in 2016 38.6 percent of

⁸ US Chamber Global IP Index, Sixth Edition, February 2018, http://www.theglobalipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_2018.pdf

⁹ http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_187510.pdf

¹⁰ National Science Board, Science and Engineering Indicators 2018 Report, Table 2-10, Appendix Tables 2-16 and 2-26

¹¹ National Center for Science and Engineering Statistics, "Survey of Earned Doctorates," National Science Foundation, <https://www.nsf.gov/statistics/2018/nsf18304/datatables/tab17.htm>

academic science and engineering publications with authors based at U.S. institutions were co-authored with institutions in other countries.¹²

C. Promote laws and policies on commercial activities and competition that are robust, transparent, and encourage foreign investment

12. Biotechnological research and development is a long-term prospect. Companies create products and health solutions that may take many years and millions of dollars to bring to fruition. When economies compete to attract this type of high-value, high-risk foreign direct investment, predictable legal environments, fiscal policies, and business frameworks that support competition are crucial. This includes business environments that reduce administrative burdens and that are thus conducive to investment in research and development. Public competition policy and public procurement for technology-based goods and services can also encourage investment in innovation.¹³ By recognizing the private sector's needs, States Parties can promote laws and policy initiatives that foster innovation and minimize investment risk, thereby increasing the investment and technology transfer they can attract.

13. The United States provides international assistance to enhance other countries' national competition policies and business environments, as well as to aid improvement of their systems of governance. This includes support for the design and implementation of antitrust laws, and laws and regulations related to investment and investor protections. Programs also support legal and institutional reform to improve governance and make policies more transparent, as well as provide assistance to help the different agencies of a government operate more effectively in the trade policy arena. In fiscal year 2017, the United States obligated 38 million dollars to these programs, providing 136 activities in 65 countries.¹⁴

14. The Department of Commerce plays a significant role in this type of outreach through its Commercial Law Development Program (CLDP). The CLDP designs and implements conferences and workshops, utilizes long and short-term advisors, and trains foreign delegations in the U.S. and other countries to improve foreign governments' commercial legal frameworks. Members of the CLDP work with requesting governments to create effective and reliable political, commercial, and legal institutions that are critical to fostering attractive environments where businesses can find opportunity. Since its inception in 1992, the CLDP has worked with more than 50 foreign governments providing thousands of seminars, workshops and consultative services. Technical assistance ranges from consultation on legal reform and the revision of commercial laws, to providing practical expertise on implementing those laws to ensure compliance.

D. Support regulatory infrastructure and frameworks that promote trade and foreign direct investment

15. Regulatory policy remains a potent means of stimulating economic activity. Eliminating undue regulatory barriers for international companies can be critical for countries looking to attract investment or technology transfer from such companies. Equitable regulations and standards for both national and international firms, and products imported or manufactured locally, can encourage foreign direct investment. Investment opportunities also

¹² National Science Board, Science and Engineering Indicators 2018 Report, Table 5-26

¹³ United Nations Economic Commission for Europe, National Innovation Systems and Policies Good Practices and Policy Recommendations, 2013

¹⁴ <https://tcb.usaid.gov/>

emerge from markets where there is already local demand or where specific health needs have been identified and related efforts are taking place. Even related public-sector innovation in these fields benefits from robust legal and regulatory frameworks. States Parties can provide incentives to encourage technology transfer by ensuring their regulations support open, equal market transactions and partnering with companies to fulfill local product demand and build capacities to solve national health problems.

16. The United States provides assistance to help minimize countries' technical barriers to trade, and in fiscal year 2017, obligated 14 million dollars for 20 activities in 15 countries to do so.¹⁵ This assistance attempts to ensure that regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade and investment. The United States Agency for International Development (USAID) is the biggest sponsor of these activities. Programs such as its Trade and Investment Hubs work in close partnership with governments in Africa to improve trade facilitation, level the playing field, promote compliance with intra-regional and international trade agreements, and reduce costs and burdens to investment and trade.

III. Looking to the Future

17. While assistance is available to make strides in these areas, States Parties can also create policies to attract foreign direct investment in their biotechnology fields on their own. A 2018 report commissioned by the Biotechnology Innovation Organization (BIO), which represents more than 1,100 companies, universities, research institutions, investors, and other entities in more than 32 countries, outlines a set of universal principles and factors that heavily influence whether or not a given economy is likely to have success in stimulating the development of its biotechnology industries. While acknowledging that no two countries' biotechnology sectors, experiences, and circumstances are the same, it is possible to identify certain policies that States Parties can adopt that will make it easier to attract foreign direct investment and develop a robust national biotechnology sector.¹⁶

18. A growing number of emerging economies are making expansion of their biotechnology industries a national priority, and have announced national strategies to develop key technologies and advance innovation. Such strategies can be of vital importance in helping countries define the role of biotechnology in their national interests; identify short- and long-term goals; and make policy commitments to achieve those goals. These strategies can improve coordination among various government agencies, promote review of national regulatory systems, and identify practical measures to improve legal commercial environments to attract foreign direct investment. While these strategies are in various stages of implementation, the experiences of countries that have designed and implemented them thus far suggest that adopting a pragmatic, long-term approach is key to reaping the economic and social benefit of biotechnologies.¹⁷

¹⁵ *Ibid*

¹⁶ Pugatch Consilium, "Building the Bioeconomy 5th edition: National Biotechnology Industry Development Strategies Globally," http://www.pugatch-consilium.com/reports/Building_the_Bioeconomy2018.pdf

¹⁷ *Ibid*

19. In summary, innovations in biotechnology and global health are increasingly made in the private sector.¹⁸ States Parties can encourage private sector partnerships and avail themselves of the benefits that cooperation with private industry offers by creating environments in which these industries can thrive.

¹⁸ National Science Board, Science and Engineering Indicators 2018 Report, Table 4-6