**APEC Life Sciences Innovation Forum**

**Policy Dialogue on Enabling Investment in the Innovative Life Sciences**

**15-16 May 2019 | Viña del Mar and Santiago, Chile**

**Executive Summary**

The life sciences are an engine of economic growth, sustainable development and medical innovation. Operating on the cutting edge of technology and employing over 5 million globally, the life sciences sector invests nearly US$150 billion each year in research and development to understand disease and create medicines and vaccines. Economies that participate in the global life sciences ecosystem can reap significant benefits in terms of enhanced economic and health outcomes and leverage it as a springboard to drive broader innovation and investment across the economy.

To explore how to foster and accelerate innovation, the APEC Life Sciences Innovation Forum (LSIF) convened a Policy Dialogue on Enabling Investment in the Innovative Life Sciences on 15-16 May 2019 in Chile on the sidelines of the Ministers Responsible for Trade Meeting (MRT). Participants included officials from government, start-ups, investment firms, global businesses, think tanks and academia. The event featured panels and presentations exploring challenges and opportunities for unlocking investment and how APEC economies can foster vibrant life sciences ecosystems through trade, investment, innovation and other policies and initiatives.

Key themes of the Policy Dialogue included:

* **The vital role that trade, investment and innovation policies play in incentivizing private sector investment in the innovative life sciences.** Economies must remove policy barriers and create a pathway for a return on investment, including through intellectual property rights, to unlock capital for life sciences innovation.
* **The opportunity for greater cross-ministerial collaboration to advance innovation.**  Trade ministries as well as other government ministries such as finance and science have important roles to play with health ministries to develop and advance coordinated strategies for life sciences innovation. Public consultation is also important to support these efforts.
* **Government, industry and academia must strengthen partnerships to develop strong innovation ecosystems that promote commercialization.** Vibrant ecosystems are essential to transforming research into new products that can be commercialized and improve health outcomes. But such ecosystems will not develop without the right policies, best practices, access to capital, and other essential elements.
* **The importance of other enablers such as human capital, regulation and standards.** These other factors include developing a strong base of human capital for the life sciences and leveraging standards and regulations that promote the development and commercialization of life sciences innovations.

Participants also discussed a variety of opportunities for future work in APEC to engage trade ministries and other stakeholders through further dialogue, policy development, and technical efforts to advance investment in the innovative life sciences.

**Role of Trade, Investment and Innovation Policies**

Trade, investment and innovation policies play a vital role in incentivizing investment in the innovative life sciences. At the two-day Policy Dialogue, former Deputy U.S. Trade Representative Robert Holleyman emphasized how innovation has become a central topic of discussion in economic and trade integration efforts, much more so than just 15 or 20 years ago. Several APEC member economies have taken steps forward in advancing innovation enabling policy provisions as part of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership and as part of the U.S.-Mexico-Canada Agreement (USMCA). Other trade discussions in the APEC region, such as the Regional Comprehensive Economic Partnership (RCEP), the Pacific Alliance’s FTA negotiations, and the proposed Free Trade Area of the Asia-Pacific (FTAAP) offer potential opportunities to advance enabling policies to unlock investment for innovation.

Speakers also raised the importance of intellectual property (IP) rights for enabling investment in the innovative life sciences. The primary factor that has allowed economies to foster transformative innovation is the ability to marshal private resources and direct them towards risk-taking activities that enable innovation, according to Patrick Kilbride of the Global Innovation Policy Center (GIPC). This allocation of resources is only possible with a system of property rights and legal certainty that creates a pathway to return on investment. Mr. Kilbride also noted that this IP infrastructure is a key factor for economies seeking to advance from a middle-income to high-income level. However, there remains significant variance in the level of IP protection around the world. Almost 25 years after the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement came into force, no economies score exactly alike in the GIPC’s annual International IP Index.

There are additional opportunities where international trade and economic policies could help foster investment in life sciences innovation. For instance, speakers noted that APEC might play a role in helping to enable cross-border access to capital, particularly for smaller economies that may need external financing to support innovation. Speakers also discussed the importance of ensuring that international cooperation in the innovative life sciences can continue even as some economies consider new measures on innovation for security reasons.

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| **Chile Case Study**  Chile is keen to ensure new medicines and technologies can reach its patients, according to Dr. Paul Daza, Undersecretary of Public Health, who opened the second day of the Policy Dialogue. Chile recently established a Ministry of Science, Technology, Knowledge and Innovation to coordinate national research efforts. While Undersecretary of Science Dr. Carolina Torrealba acknowledged that Chile is not a major player in biomedical research and may never be the global leader, there are still many compelling reasons for Chile to support the life sciences, including to participate in global knowledge conversations and make better health and public health decisions. Chile is running in the knowledge race not to win but to be part of the future.  Chile has a strong education system, but this has not translated into many life sciences products. Some innovators leave Chile to pursue their goals, since finding money at early seed stages for biotech can be challenging, and many universities do not understand how to commercialize new innovations, according to Markus Schreyer of Ganeshalab. A strong support system, including clear rules around intellectual property and technology transfer and a long-term innovation strategy, could help to enable life sciences companies to stay and grow in Chile. Despite these challenges, investors and innovators continue seeking to demonstrate that life sciences innovation can thrive in Chile. Alex Seelenberger of the Chilean venture capital firm Aurus noted that start-ups are still pushing forward and leaping into the unknown despite broader cultural challenges facing entrepreneurship. Several health-focused start-ups have formed collaborations in other APEC economies, including to obtain additional financing. If some of these companies can get through clinical trials, they can demonstrate that world-class health work can be done in Chile. One such company, Andes Biotech, already has over 65 patents and recently began a new phase of clinical trials in Chile. Collaboration with counterparts in other APEC economies has helped support Andes Biotech at each stage. But the company has had to face various challenges along the way, such as a lack of role models, immature regulatory framework and doubts about securing local capital.  There is significant opportunity for Chile to enhance its policy frameworks to foster greater investment and innovation. Several important efforts are underway. Dr. Carolina Sepúlveda of the Ministry of Foreign Affairs described the government’s efforts to address key challenges in the tech transfer/development phases of innovation, such as by seeking to make funding more flexible in time and amounts and seeking to foster increased coordination across government to identify pitfalls in existing regulations and propose new regulations. At the same time, it is vital that Chile maintain the advantages it already has. Natalia González of Libertad y Desarrollo expressed hope that policies under consideration in the Congress as part of the Fármacos II legislation would be adjusted to avoid liming IP rights and fixing prices in ways that could discourage innovation and potentially raise questions related to the TRIPS Agreement. |

**Importance of Cross-Ministerial Collaboration**

There was broad agreement among speakers at the Policy Dialogue that a range of government stakeholders, including trade ministries, have crucial roles to play in fostering investment in the innovative life sciences. Trade ministries have particular expertise in areas such as intellectual property, regulatory barriers and market access that are key to developing an enabling environment for innovation. Other ministries such as finance, science and foreign affairs also have relevant areas of expertise. But ministries often operate in siloes, and are not always engaged in efforts to promote life sciences innovation despite the important expertise they can offer. Finding ways to engage with this broader range of stakeholders, including within the APEC process, will be an essential step to advance further investment in innovation.

There was also agreement that translating broader ministerial engagement into inter-ministerial collaboration is also crucial to making progress. One idea suggested was for economies to consider holding quarterly task force meetings between relevant ministries on their life sciences innovation strategies and to consult with public stakeholders as part of this process. Several economies have already experimented with various forms of inter-ministerial cooperation. Thailand has convened meetings between ministries of health, science, and higher education to prioritize efforts and identify synergies. The Queensland Government in Australia has also sought to bring together a broad range of governmental stakeholders to coordinate efforts to advance the life sciences, including departments for science, innovation and state development. Economies that can mobilize and coordinate a broad set of ministries behind a national innovation strategy will be better positioned to ensure their policies and initiatives are working collaboratively to advance the innovative life sciences. Public consultation can also be helpful to inform these national efforts and identify challenges and priorities.

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| **Australia Case Study**  The Australian state of Queensland has undertaken a multi-year effort to promote life sciences as part of its local development strategy. As outlined by Dr. Mark Jacobs of the Department of Environment and Science in the Queensland Government, the state has maintained bipartisan support for the life sciences as an economic plank through seven changes of government. When its efforts began, Queensland was below the national average on metrics such as R&D and income and seeking to diversify its economy to focus more on knowledge intensive industries. While ensuring foundational elements like regulatory systems and IP were in place, Queensland has pursued a “Bricks to Brains to Business” strategy, beginning with investment in R&D infrastructure such as new biomedical facilities (“Bricks”), followed by an emphasis on enhancing human capital in partnership with universities (“Brains”) and then focused on entrepreneurship to get products out of labs to markets (“Business”). As part of the latest efforts, a key priority has been promoting connections between public sector researchers and industry. They also continue to explore opportunities to improve access to capital: after an initial 10-year investment fund did not provide the economic returns they expected, they have since launched an investment effort with a private partner. So far this model has fared better due to the added expertise and connections it has brought to bear, but they continue to explore new ways to expand access to capital for their scientists and universities and achieve their goal of making Queensland a center for life sciences innovation. |

**Need to Promote Vibrant Innovation Ecosystems**

While greater collaboration within governments is important, success also requires nurturing vibrant innovation ecosystems that promote commercialization by bringing together government, industry and academia. Sandeep Patel of the U.S. Department of Health and Human Services (HHS) shared how the United States has created a new Division of Research, Innovation and Ventures (DRIVe) to help foster public-private partnerships with universities, investors, and other stakeholders and de-risk investment in innovation around key health threats. Various enabling policies have helped to foster innovation ecosystems, including the U.S. Bayh-Dole Act, which has promoted tech transfer between universities and industry partners. How health coverage programs such as Medicare pay for certain products is also important for how investors view the development of products for certain issues. Other economies have leveraged policies to address their own unique challenges towards promoting innovation ecosystems and commercialization. In the case of Thailand, many researchers work in the public sector as part of government or academia. To promote greater commercialization, a program was launched to allow researchers to be “rented” to private companies to better facilitate the flow of talent between the public and private sectors.

But fostering innovation is not only about changing policies, as Juan Diddi of Bristol-Myers Squibb noted; it is also about driving collaboration and communication between public and private sectors. For instance, the U.S. Food and Drug Administration (FDA) has started to have conversations earlier and earlier with companies to try to speed up the market entry of new products. Speakers suggested that universities in APEC could seek to share and learn best practices from one another on how to partner with industry in order to foster entrepreneurship and commercialization ecosystems. Participants also noted that industry has important expertise to offer government, including on issues such as how to bring products to market as well as how to deploy financing at a larger scale.

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| **Singapore Case Study**  Singapore has made major strides in building a life sciences industry over the last two decades. As a small city-state, it has depended on its human capital to drive growth in new industries, in combination with strong rule of law and strong IP protections, according to Dave Goh of the Singapore Economic Development Board. Singapore launched a biomedical science initiative in 2000, and today the sector has over 25,000 employees and the economy is home to over 50 biomedical manufacturing plants as well as R&D facilities. Singapore sees future healthcare characterized by new innovations in areas such as patient centric care, precision treatment, and digital health, and the economy is keen to partner with companies to take advantage of these shifts. The government has also set aside public research funding to prioritize R&D investment in specific disease areas, with the goal of deepening its capability to develop new products. Singapore is now seeking to attract more venture capitalists, incubators and partnerships with multinationals. Overall, the economy has embraced an “ecosystem approach” so as to remain relevant to companies seeking to innovate. |

**Other Factors to Enable Innovation**

Many other factors also serve as building blocks to construct an enabling environment for investment in life sciences innovation. Several speakers highlighted human capital as one of the most important drivers of innovation. Economies have to grapple with a variety of new challenges in developing sufficient human capital, including rapidly changing talent needs due to innovation, an increasing demand for professionals to have a mix of “hard” and “soft” skills, and the issue of retaining talent to avoid brain drain. APEC has made important initial progress in building human capital: as outlined by Dr. Nares Damronchai, the LSIF Government Co-Chair and CEO of the Thailand Center of Excellence for Life Sciences, since its launch the APEC Biomedical Technology Commercialization Training Center has already trained over 500 policy makers and university-based technology transfer professionals in the essentials of tech transfer and commercialization in the innovative life sciences sector. But there could be further opportunities for APEC to explore to advance human capital in the life sciences.

Standards and regulations can also serve to create an enabling environment for innovation. While standards are not often discussed in the innovation context, they play a vital role in facilitating the diffusion of innovation by providing greater regulatory predictability and increasing trust, particularly in cutting edge areas such as biologics medicines and digital therapeutics, noted Anthony Lakavage of USP. In fact, quality standards experts work across industry, academia, and regulators to keep pace with technology, creating standards that when used can more readily enable quality production at a scale and consistency that’s needed for global markets. Regulatory processes for approval of new biopharmaceutical products are also a vital part of the equation if innovation is to be enabled and incentivized. Dr. Dino Sepúlveda of the Chilean Ministry of Health underscored the importance of transparent decision-making processes with broad stakeholder consultation to allow society, patients and industry to all participate is essential to enhance accountability and give legitimacy to decisions.

**Future Opportunities for APEC**

The Policy Dialogue provided an opportunity to revisit the LSIF Enablers of Investment Checklist, which was developed in 2008 to allow economies to measure their progress against a series of key indicators. Dr. Nares Damronchai underscored that “all enablers matter,” and that even if an APEC economy performs well in one, if it is not doing well in one that will affect its overall performance. Speakers broadly agreed on the value of the Checklist, but underscored the need to continue to advance work to ensure all APEC economies are leveraging the Checklist through national strategies to advance the innovative life sciences. APEC can provide support through continuing to convene further dialogues, developing and sharing policy models and best practices and leading technical projects and initiatives. Potential future efforts might include:

* Developing a policy toolkit for ministers of trade to show what types of policies they can leverage to foster life sciences innovation through trade and investment frameworks
* Compiling examples of how governments have fostered cross-ministerial collaboration to advance innovation and the life sciences, and how these models can be strengthened and replicated across APEC
* Helping to catalyze the development of innovation ecosystems, such as by working with academia to accelerate the sharing of best practices on industry-university partnerships or exploring opportunities to expand access to capital and support for start-ups
* Convening further dialogues on how other enablers, such as standards, regulation and human capital can be leveraged and enhanced to better promote life sciences innovation