

APPENDIX 8

Principles for Developing the Innovative Health and Life Sciences Sector in APEC Economies

Innovative Biopharmaceuticals, Medical Devices, Health Products & Services

The over-arching objective of the development of the innovative health and life sciences sector is to generate health and wealth outcomes.

1. Health Outcomes: achieve cost-effective improvements in the health of populations through investment in initiatives and innovations that support quality care, and provide the foundation of a quality health care system, consistent with multilateral agreements to which APEC economies are party, and international best practices.
2. Wealth Outcomes: Drive job creation and economic development through attracting private sector investment in all aspects of the life sciences value chain.

The principles for developing the innovative health and life sciences sector in APEC economies are a guide for economies to use as a reference when formulating their domestic policies to encourage innovative health and life sciences development.

Principle	Justification
Support an Open Economy, Including Free Trade & Investment	
1) Develop and maintain an open economy as defined in the open and competitive markets section of the LSIF Enablers of Investment Checklist that promotes the flow of capital, people, ideas, goods, and services across borders in ways that ensure competition, enhance productivity, and foster growth, keeping in mind public health and safety imperatives.	<ul style="list-style-type: none"> • An open economy will foster a culture of theoretical and applied scientific research and help grow the pool of top quality scientists, business developers, and entrepreneurs required for the development of an innovative life sciences sector.
2) Promote open investment in life sciences, including by working to remove or reduce restrictions on foreign direct investment in innovative life sciences and taking into consideration domestic regulation and law.	<ul style="list-style-type: none"> • An open investment environment is a key consideration for businesses looking to invest in the life sciences sector. Year after year, economies with little or no restrictions are able to attract more investment than those with investment restrictions and burdensome regulations.¹
Encourage Innovative Research & Collaboration	
3) Adopt a framework that supports cooperation and interaction among universities, public research institutions, and companies, including through joint research and development, public-private partnerships, and technology diffusion on mutually agreed terms.	<ul style="list-style-type: none"> • A framework that supports public-private partnerships and effective technology diffusion from the public to the private sector can accelerate innovation and the commercialization of life sciences innovations.

¹ For more information see the 2012 Annual *The Global Venture Capital and Private Equity Country Attractiveness Index*, available at <http://blog.iese.edu/vcpeindex/>

Principle	Justification
Provide IP Protection for Innovation	
<p>4) Provide effective and predictable protection and enforcement of intellectual property rights for the full range of innovations in the health and life sciences sector, consistent with multilateral agreements that APEC economies are party to.</p> <p>5) Ensure that IP laws including patent laws are consistent with WTO rules. Patent protection should last at least 20 years from the date the patent application was filed. The terms and conditions of transfer of technology, production processes, and other proprietary information should be left to the agreement between individual enterprises consistent with WTO rules.</p> <p>6) Consistent with multilateral agreements to which that APEC economies are party, ensure the protection of test data required for the approval of life sciences innovations and taking into consideration the complexity of these innovations. Extensive analytical, preclinical, and clinical research tests must be completed before life sciences innovations can be made available to patients.</p>	<ul style="list-style-type: none"> • Creates a legal framework including a strong IP and healthcare environment in which innovators, including small and medium-sized businesses, are encouraged to invest in the research, development, and commercialization of life sciences technologies so as to benefit patients. If a framework is well balanced, investors will naturally realize a positive return on their investment, while patients will benefit from a better range of health care options. • Ensuring the integrity of the health and life sciences innovation approval process is important. Test data, which can take several years to generate, typically require substantive commitment in research and development and investment.
Develop Effective & Efficient Regulatory Approval Procedures	
<p>7) Encourage harmonizing regulatory systems of APEC economies consistent with the agreed target of achieving regulatory convergence for medical product approval procedures by 2020. Ensure that regulatory systems are transparent, non-discriminatory, provide due process, and include opportunities for early and meaningful stakeholder engagement.</p>	<ul style="list-style-type: none"> • APEC Economies are working towards achieving regulatory convergence of medical products by 2020 with the goal of increasing investment in clinical trials and innovative product development and commercialization. • Open and transparent regulatory processes promote innovation, and result in regulations that are more relevant and effective in responding to both regulatory and market needs.
Encourage the Use of Health and Life Sciences Innovations	
<p>8) Promote utilization of innovative health and life sciences by investing in strong healthcare systems.</p>	<ul style="list-style-type: none"> • The innovative health and life sciences sector will prosper if APEC Economies welcome the introduction of new medical therapies and services into the healthcare system, create value-based markets for such products and services, and build adequate physical infrastructure to ensure their appropriate delivery.

Sources:

APEC, Promoting Effective, Non-discriminatory, and Market-driven Innovation Policy, The Honolulu Declaration: Toward a Seamless Regional Economy (Annex A) (2012).

Available at: http://www.apec.org/Meeting-Papers/Leaders-Declarations/2011/2011_aelm/2011_aelm_annexA.aspx

APEC, 2008 Committee on Trade and Investment Annual Report to Ministers, Life Sciences Innovation Forum Enablers of Investment Checklist (Appendix 7) (2008).

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APEC, Addressing the Chronic Disease Challenge in the APEC Region: An Innovative Approach to Collaborative Action (2011).

http://mddb.apec.org/Documents/2011/MM/AMM/11_amm_004.doc

Scientific American Worldview; <http://www.saworldview.com/> Provides a look at the environment for biotech and life sciences around the globe. It provides a scorecard of how well certain countries are doing in the elements necessary to create a thriving sector.