The APEC Life Sciences Innovation Forum Terms of Reference

1. The Mandate for the Forum

At the October 2002 Joint Ministerial Meeting and Leaders meeting in Los Cabos, Mexico, Ministers and Leaders endorsed the establishment of a Life Sciences Innovation Forum in APEC. Specifically, in their Decisions approved at Los Cabos, Ministers:

"... recognized members' interest in promoting public health improvement, and have made the life-sciences sector a high priority by approving the establishment of a Life-Science Innovation Forum in APEC."

Economic Leaders:

"... acknowledged that investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation. We need to be more effective with our investment at every stage of the health care process, including primary prevention against disease risks, and focusing on most vulnerable populations."

Leaders called for:

"the establishment of a life-sciences innovation forum comprising government, private sector, and academia representatives to develop a strategic plan for lifesciences innovation in the region. This should include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and lifestyle diseases which afflict our people".

The strategic plan was developed by the Forum and endorsed by Ministers and Leaders in November 2004. Implementation is underway. Projects are underway or have been completed to streamline and harmonize regulatory procedures and build capacity in clinical trials (Good Clinical Practice), quality guidelines (Good Manufacturing Practices) [GHTF], measures to combat counterfeiting of medical products...

2. The Purpose of the Forum

2.1. As instructed by Leaders, the primary goal of the Life Sciences Innovation Forum (LSIF) is to bring together representatives of the government, private sector and academia to promote life-sciences innovation in support of human health in the region in accordance with the Ministers and Leaders mandate. The Forum will provide a unique avenue to promote innovation in the life-sciences sector and at the same time support the overall APEC trade and investment agenda. Accordingly, the Forum will discuss, identify and promote a policy environment to foster the growth of life-sciences innovation and the improvement in public health in the Asia-Pacific region. In so doing, the Forum will strive to enhance the flow of information among APEC economies regarding life-sciences issues to help foster life-sciences innovation in the region and will consult with and not duplicate current and ongoing efforts of other APEC fora.

2.2. The Forum has developed recommendations for a strategic plan to address the health challenges and economic development goals identified by Leaders, including

identifying the factors that are critical to success in each segment of the life-sciences value chain. The life-sciences value chain encompasses all the value-added steps in a life-sciences product development cycle, beginning with research, continuing with development (R&D), to manufacturing and marketing, and through to consumer or patient use.

2.3. The Forum will also develop recommendations for (i) implementation of the strategic plan – in particular, implementation projects in priority areas, including research, access to capital, harmonization with international standards and health services, (ii) promoting economic and technical cooperation, including capacity building, and (iii) explore avenues to promote public-private sector collaboration in life sciences innovation. Some APEC Member Economies may choose to move more quickly than others in terms of implementing recommendations as is consistent with APEC's flexible, voluntary and consensus oriented approach to trade facilitation and economic and technical cooperation.

3. The Structure of the Forum

3.1. The LSIF will operate on the basis of consensus, and in line with agreed APEC rules and guidelines. The LSIF will be held annually, in the margins of the Third Senior Officials' Meeting.

The work program and progress of the Forum will be reported initially to the Committee on Trade and Investment (CTI) and, where appropriate, to APEC Senior Officials, Ministers and Leaders. In the course of its work program, through the Planning Group, the LSIF will consult with other APEC specialty fora and international and regional fora as appropriate. The work program and outcomes will also be conveyed to all relevant APEC fora. Using the APEC reporting structure, through the CTI, to Senior Officials, and Ministers and Leaders when appropriate, progress towards implementation of the LSIF Strategic Plan, the identification of critical issues in the life-sciences value chain and recommendations to address these will be reviewed annually.

3.2. The Forum will be supported at the working level by an ad hoc Planning Group, comprising delegations from interested economies, led by government officials and including expert representatives from the private sector and academia as appropriate. The ad hoc Planning Group will meet as needed before the Forum to determine the scope and operational structure of the Forum, determine specialty APEC fora or international bodies with which to consult, communicate, or coordinate work, define the agenda, determine the schedule of meetings, and facilitate the Forum. Schedules of meetings will be determined annually to allow flexibility. The proposed schedule of meetings in any one year, including the annual Forum meeting, will be agreed and deposited with the APEC Secretariat in a timely manner for inclusion in the APEC calendar. Because of the high level nature of the annual Forum, the date and venue for the Forum will be established within two weeks of the first senior officials meeting of the year.

3.3. The annual Forum will involve appropriate senior representatives of the lifesciences/human health sector and of APEC member economies as mandated by Leaders. The LSIF may, as appropriate and with the consensus of all member economies and in accordance with APEC guidelines for non-member participation and guest status, allow participation of guests from non-member economies to the forum.

4. Administration of the Forum

4.1. The Forum will be managed by a Chair supported by three Co-Chairs and a Board of Directors representing the tri-partite nature of the forum (life-sciences industry, academia and the public sector) and reflecting specific expertise in the core areas of the forum's work. The Chair and Co-Chairs will coordinate views and positions. They will be selected by the Forum from a list provided by the Planning Group to serve for a term of at least two years with an extension for a further two years if requested.

4.2. The Board shall comprise of 12 members representing the innovative life sciences sector and reflective of the tri-partite nature of the Forum.

4.3. A Coordinator for the Forum will be identified to disseminate information, Chair Planning Group meetings, and coordinate with the APEC Secretariat, APEC bodies and international bodies as appropriate and as identified by the Planning Group or the Forum.

4.4. To facilitate the work of the Chair and the Board of Directors of the Forum, each member economy is invited to designate up to two contact points to coordinate that member economy's participation in the Forum. Interested economies also may want to appoint a Life Sciences Champion in their economy to help coordinate and facilitate high level exchanges and implementation projects. Guidance is attached on criteria to assist interested economies in identifying a Life Sciences Champion in their economy.

4.5. The LSIF may, as appropriate and with the consensus of all member economies, establish subgroups, or expert groups it considers necessary to assist in the conduct of its work program.

4.6. The names of the Chair and Co-Chairs constituting the Board of Directors and contact details will be deposited with the APEC Secretariat by the Forum coordinator.

4.7. The LSIF has a term of four years starting from March 2018. At the expiration of this and any subsequent term, the mandate of LSIF and its ToR shall be reviewed by LSIF and the Committee on Trade and Investment (CTI), and a recommendation on renewal shall be put to Senior Officials for approval.

4.8. Quorum for LSIF's Meetings constitutes a total of 14 economies participating in LSIF meetings during a SOM. Should the LSIF fail to meet quorum for two consecutive SOMs, it shall be referred to Senior Officials for a decision on whether it should continue to exist.