
**APEC LIFE SCIENCES INNOVATION FORUM
STRATEGIC PLAN**

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Message to Leaders

APEC members face challenges to their healthcare systems and to ensuring public health as never before. We recognize that improving the health of our population involves early detection, prevention and innovation at many levels. Technological advances and continuing innovation in the life sciences sector offer hope, and a real opportunity to advance public health, while promoting economic productivity and development. The APEC region is poised to take a leadership role in developing a model for regional cooperation to promote and support bio-medical life sciences innovation to stimulate economic growth and improve the quality of life for its people.

Recognizing the potential of life sciences innovation as a new driver of economic growth and a potent contributor to socio-economic well being, and the benefits of a collective approach to this sector, you directed us to establish a life sciences innovation forum to develop a strategic plan for life sciences innovation in the region. You also asked that the plan “include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and life-style diseases which afflict the people of the region.” In so doing, you stated that “investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation” and that “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.”

With this mandate, we have developed for your review and endorsement a strategic plan, which serves as a set of best practices guidelines to promote life sciences innovation in the region. The imperative for implementation of this plan has been made all the more pressing by the current focus on health priorities in the region, something we have factored in to the plan to ensure both a responsive and a long-term perspective on health policy, and as a guide for more effective investment in innovation. The plan acknowledges the unique social and cultural environment of each economy.

Our overarching messages are that, the region’s competitiveness and the health and well being of our people, would benefit from (1) a top-level political commitment to this sector with appropriate resource allocation, and (2) an integrated approach taken to life sciences and health care policy making. Many different agencies have competing priorities and approaches. Coordination of these will maximize benefits to the community and efficiencies in the administration of government systems in this sector.

We also advocate a multidisciplinary and inclusive approach to health care and life sciences innovation policy-making, bringing together stakeholders from the government, industry, academia and the community to identify economy specific priorities and debate issues before they become counter-productive areas of contention. You established the Life Sciences Innovation Forum as a tri-partite mechanism. This has stimulated extremely productive debate, solid outcomes for the strategic plan, and innovative recommendations going forward.

The strategic plan is structured to (1) allow economies to determine the overarching regulatory and policy environment that would support social and economic goals related to life sciences innovation in the region and lay the foundation for a more coordinated approach to identifying and tackling health priorities; and, (2) allow an economy to decide how the four areas of the life

sciences innovation value chain (research, development, manufacturing and marketing, and health services) could be most productively developed and aligned to encourage economic growth and social well being.

We start with basic principles governing life sciences innovation, which were identified as common themes at the August 2003 inaugural Life Sciences Innovation Forum in Phuket, Thailand. These basic principles should be applied individually and collectively. Working with these basic principles Expert Working Groups developed goals, operating principles and best practices for each area of the life sciences value chain. The September 2004 2nd Life Sciences Innovation Forum in Penang, Malaysia developed recommendations for collective action going forward. To support implementation of the strategic plan, we have developed a Life Sciences Innovation Readiness Assessment template for interested economies to use to assess their strengths and capacity building needs in each area of the life sciences innovation value chain.

The Life Sciences Innovation Forum considers that implementation of this strategic plan will provide a model for a global approach to life sciences innovation. Our region already has a comparative advantage in this sector and we should capitalize on this. We believe that the people of our region will benefit significantly from a coordinated approach to this sector's development, and that resources will be spread more efficiently and evenly throughout the region. Our work has already attracted international recognition. Because of the forum's work on the harmonization of standards, the International Conference on Harmonization (ICH) invited the LSIF to send a permanent representative to the ICH Global Cooperation Group meetings. The LSIF now is an active member of the group. There is work underway to launch a series of Pacific Health Summits beginning in June 2005 to focus on early detection and disease prevention, which may give rise to outcomes consistent with your instructions in this critical area.

Finally, we stress the importance of continuing dialogue among all stakeholders during the implementation phase of the strategic plan. Industry and academia have many resources to help economies build capacity in this sector. Effective implementation also requires community involvement. We recommend that you endorse the concepts and principles in the strategic plan and instruct the Forum to develop, for interested economies, a road-map for implementation according to the attached schedule. In seeking your endorsement of these principles and recommendations, we also recognize the many ongoing activities within APEC that may support the recommendations of the LSIF. We further encourage interested Economies to develop specific implementation milestones and establish multidisciplinary implementation task forces involving all stakeholders to assess priorities, needs, enhance public awareness, and monitor progress.

Respectfully submitted
H.E. Suwit Khunkitti
Chair, Life Sciences Innovation Forum
November, 2004

Background

At their October 27, 2002 meeting in Los Cabos, APEC Economic Leaders called for the establishment of a tri-partite Life Sciences Innovation Forum (LSIF) “to develop a strategic plan for life sciences innovation in the region”. Leaders mandated that “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”. In so doing, Leaders acknowledged that “investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation” and that “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”. Terms of reference were agreed for the LSIF (Appendix I) in Chang Rai, Thailand, in February, 2003. The inaugural forum was held August 14-15, 2003 in Bangkok, Thailand under the chairmanship of H.E. Suwit Khunkitti, then Deputy Prime Minister of Thailand. The second LSIF was held September 16-17, 2004 in Penang, Malaysia.

The forums attracted world-wide attention. Experts from government, academia and industry participated. Key outcomes of LSIF I are attached as Appendix II. LSIF II outcomes are reflected in the strategic plan. The first LSIF developed a framework for the strategic plan based on the four main elements of the life sciences innovation value chain: Research, Development, Manufacturing and Marketing, and Health Services. That forum recommended that because life sciences technology is fast moving, the strategic plan be finalized for review and endorsement by APEC Economic Leaders at their November 2004 meeting in Santiago. Ministers and Leaders agreed with this recommendation, among others from the forum at their October 2003 meetings in Bangkok, Thailand.

Ministers further recommended the establishment of Expert Working Groups to work on specific elements of the strategic plan covering each of the four areas of the value chain. Two meetings of the Expert Working Groups were convened: February 12-13, 2004 in Khon Kaen Thailand and June 11-12, 2004 in Washington DC. An ad hoc Planning Group open to representatives of all APEC economies met at each senior officials meeting throughout 2002 – 2004 to review and comment on progress. Ministers also “supported the forum’s recommendations to identify economy-specific strengths in life sciences and ways to promote trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation”. Accordingly, the Expert Working Groups developed a readiness assessment template to assess the strengths and capacity building needs of economies. In June 2004, APEC Trade Ministers broadened the mandate of the forum in acknowledging the potential of the strategic plan to promote global trade and investment in innovative life sciences products and services. Two APEC readiness assessment pilot projects were conducted in 2004 supported by APEC funds. The results were presented to LSIF II on September 16, 2004 in Penang, Malaysia.

This strategic plan has been developed from the work products of the first and second Life Sciences Innovation Forum, the Expert Working Groups and, the APEC Life Sciences Planning Group meetings. It has been reviewed by the second Life Sciences Innovation Forum in Penang, Malaysia and by APEC Senior Officials at their October 3-4, 2004 meeting in Santiago.

Executive Summary and Recommendations to Leaders

- For the purpose of the strategic plan the term “life sciences” refers to bio-medical sciences as they relate to human health.
- The Life Sciences Innovation Forum has developed a strategic plan for endorsement by APEC Economic Leaders based on the common themes and principles that emerged from the 1st and 2nd Life Sciences Innovation Forums and the work product from the Expert Working Groups as instructed by Ministers and Leaders. The Forum agreed that investment in life sciences innovation by APEC member economies would contribute significantly to the longevity, wellness and economic potential of the region and help address critical areas of concern including early detection, prevention and treatment of diseases. Thus the plan has been constructed to provide guidance on how best to maximize the return on investment in health innovation and turn activities in this sector to the benefit of people in APEC economies.
- The LSIF recognizes the existence of many ongoing activities within the APEC organization that may already support the recommendations of the LSIF. The Forum does not intend to duplicate these activities, or activities of other organizations, but would support these activities to meet the goals of the LSIF. Because the LSIF is designed to create an enabling environment for life sciences innovation and encourage cooperation among the APEC economies to achieve the LSIF goals, LSIF recognition of these programs may help facilitate these activities, especially capacity building programs.
- The strategic plan covers the four key areas of the life sciences innovation value chain: research, development, manufacturing and marketing and health services. The chain has been described in this way to facilitate economies in identifying the differing needs and capacity building relevant to each, and also to emphasize the role of health services and health policy making as a mechanism for translating life science innovation into improved access to innovation and improved health for patients. This includes approaches both to health policy making and to the delivery of health services.
- In each of the four areas, principles and, where possible, best practices have been identified that would contribute to a more efficient, effective, and coordinated policy approach to support innovation and health in the region. This would enhance the productivity and well-being of the people and also help address the health challenges of existing and emerging diseases in the region that undermine the well-being of vulnerable populations and have the potential for large adverse impacts.
- Based on the output from the Forum and Expert Working Groups, the Forum developed a Life Sciences Readiness Assessment template so that interested economies can best decide how their investment in the life sciences sector would be the most productive and bring the most benefit.

Recommendation: Endorse the principles and concepts of the strategic plan as a best practices guideline for the region to follow individually and collectively in the life sciences sector to improve the health and well-being of citizens while supporting economic development goals.

Recommendation: Instruct LSIF to develop, for interested economies, a road-map for early implementation of the strategic plan based on the principles, concepts and best practices so identified and the attached implementation schedule.

Recommendation: Support and encourage interested economies to finalize and utilize the LSIF Readiness Assessment template, undertake readiness assessments in 2005 and, on that basis, help them develop economy-specific implementation schedules with clearly identified milestones.

Areas of Priority Focus

- Efficient and effective investment in and support for life sciences innovation requires a transparent, coordinated, and holistic approach to policy and priority setting, and to resource level and allocation, with the involvement and commitment of all stakeholders (within government, industry, academia, and the community). In this way, in each economy, the needs of populations can be best identified and addressed and targeted activities can be more evenly spread to where they will be most productive.

Recommendation: Encourage each APEC Economy to consider establishing Economy-specific multidisciplinary taskforces to make recommendations on life sciences policy and priorities across all areas of the health care process.

Recommendation: Consistent with Leaders' commitments on transparency, encourage each Economy to publish for comment advance notice of policy development, policy review and outcomes covering this sector and establish a consultative mechanism involving all stakeholders.

Recommendation: Welcome Thailand's offer to host a Ministerial level meeting in the 2nd quarter of 2005 to discuss and examine examples of effective holistic approaches to life sciences innovation that result in more effective and coordinated actions aimed at meeting the health needs of all populations.

- Attracting and retaining a dynamic life sciences industry depends heavily on the existence of an enabling environment for innovation. As such, the protection of intellectual property and the existence of rule of law that protects innovators is viewed as a precursor to the development of a robust life sciences sector in the region.

Recommendation: Encourage APEC-wide enactment of WTO-TRIPs by all member economies with adequate and effective infrastructure and resources to enable rightholders to enforce their intellectual property rights and criminal prosecution of counterfeiters of medicines across the region.

Critical Infrastructure

- Efforts towards critical infrastructure development to international standards (biomedical facilities and supporting information technology platforms) and human capital development in the life sciences sector can benefit from a regional approach involving activities including, but not limited to, public-private sector partnerships in the design, establishment and implementation of appropriate programs.

Recommendation: Building on current initiatives in APEC member economies, instruct officials to examine the feasibility and prospect of interested economies establishing a regional Molecular Biology Laboratory (drawing on the model of the European Molecular Biology Laboratory), as well as the prospect of other relevant regional facilities such as chemical pilot and production plants and analytical facilities.

Recommendation: Direct the Life Sciences Innovation Forum to commission a study of the potential for cooperative development of innovation and applications platforms for the life sciences. The study should include an examination of real needs of member economies and how these might be met by a cooperative program.

Education

- Education and human capital development are recognized as necessary for the discovery of new innovation, the encouragement of the utilization of innovation and the subsequent appropriate use.

Recommendation: Encourage APEC Education, Health, and Science and Technology Ministers to give appropriate priority to life sciences education and continuing medical professional education and training as described in the strategic plan.

Recommendation: Encourage APEC members to develop and implement life sciences curricula at all education levels. Encourage exchange programs on life sciences among APEC Economies at secondary and tertiary levels. In so doing, develop coordinated post-doctoral fellowship programs dedicated to life sciences.

Recommendation: Encourage the development of patient information and education, such as disease awareness programs and information on the full range of treatment and management options for important disease areas (including, for instance, dietary and lifestyle advice, as well as self-care).

Recommendation: Without duplicating other organizations, encourage the establishment of a federation of regional life sciences professional societies that may in turn be recognized by international professional societies.

Capacity Building

- Capacity Building in all areas will be critical to the successful implementation of the strategic plan. Multilateral, regional and bilateral public/private sector partnerships should be encouraged to this end. LSIF Readiness Assessments by interested economies will help identify economy-specific capacity building requirements.

Recommendation: Encourage capacity building in health technology assessment so that economies are able to make informed decisions on health care and the introduction of new health technologies.

Recommendation: Endorse the establishment of expert taskforces on life sciences capacity building to conduct the Readiness Assessments in conjunction with facilitators and to use the assessments to identify gaps and facilitate the provision of necessary life sciences capacity building.

Recommendation: Welcome the establishment of a life sciences innovation *ad hoc* Technical Working Group to support the further development and the implementation of the Life Sciences Readiness Assessment and note that the first meeting of the Technical Working Group will be hosted by Thailand in the 2nd quarter of 2005.

Access to Capital

- Access to capital was identified as a key factor in supporting the development of innovative products and services in the region. Among other things, it is a determinant on whether an innovation can be developed and brought to the consumer efficiently and effectively.

Recommendation: Instruct officials in interested APEC economies and the private sector to jointly explore the prospect of establishing a Regional Venture Capital facility directed at accelerating devices, diagnostics, medicines and other treatments for the diseases of the developing economies, and at emerging prospects from developing member economies.

- In consultation with the Technical Working Group of the Finance Ministers process, interested APEC economies should establish task force of experts to develop options for consideration by economies individually and collectively.

Recommendation: Examine the feasibility of establishing a Cooperative Program between Member Economies' Health Research Funding Bodies to identify and fund high quality research in member economies as described in the strategic plan.

Recommendation: Explore best practices for economy-specific fiscal incentives to attract R&D, manufacturing and commercial operations into the region consistent with existing international obligations.

Harmonization

- Harmonization of standards for life sciences products and services (Appendix X provides an indicative list) and mechanisms for collaboration and the exchange of information among

economies were recognized as critical elements in all areas of the life sciences value chain and a basic principle going forward. To maximize the region's ability to address the region's health needs in the four areas of the value chain, policies, standards and regulatory mechanisms should be reviewed against international best practices, in accordance with APEC principles on harmonization.

Recommendation: Instruct the Forum to develop a mechanism for reviewing progress and the harmonization of standards against international best practices.

Recommendation: Noting that APEC LSIF has permanent representation on the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH) and that APEC member economies also participate in other Life Sciences standards bodies such as the Global Harmonized Task Force for medical devices, APEC Leaders agree in principle to move toward a regional harmonization process amongst APEC economies with a view to achieving close collaboration, international standards and global best practices through collaboration with bodies such as the GHTF, the Agenda for Leadership Program and Health Care Accreditation (ALPHA), and the ICH GCG and instruct LSIF to develop a roadmap to achieve this goal for life sciences products and for services.

Recommendation: Encourage information sharing among regulators with regard to safety issues, counterfeit products and other risks.

Detection and Prevention

- Building on the strategic plan, cooperative projects are underway to develop the necessary innovations to address early detection and prevention of diseases in the region. For example, an independently supported Pacific Health Summit will be held in June 2005 to focus on new technologies in early detection and prevention of diseases and policies to support these emerging technologies. The APEC Health Task Force also is addressing health priorities, including health security threats in the region, and independent initiatives are being promoted by major research organizations in the region.

Recommendation: APEC Leaders welcome the launching of a series of independently supported Pacific Health Summits beginning in June 2005 involving stakeholders in the early detection and prevention of diseases in the region and discussion of policies to support associated emerging technologies.

Recommendation: Where appropriate, LSIF should ensure that cooperative programs are conducted in coordination with the APEC Health Taskforce.

Recommendation: APEC Leaders to note that a number of APEC member economies have expressed interest in participating in a major molecular diagnostics initiative to help reveal the early onset of chronic diseases and an associated large scale cohort and monitoring program to gather essential information for the assessment of risk and early disease intervention.

Health Care Policy and Health Service Delivery

- Improved approaches to health care policy making and priority setting has been identified by the LSIF as a key part of the process to improving the health of populations in APEC economies and reducing inequalities. This brings important social and economic benefits. For life science innovation to support this, economies not only have to consider how they support the development of innovation, but also how those innovations are put into practical use to bring benefits to patients. Securing patients appropriate access to innovation happens most effectively when policy making, research development, the allocation of health resources and the delivery of health care is coordinated in a way that is focused on the needs of populations.

Recommendation: Encourage economies to identify and prioritize the health needs of the populations and to identify mechanisms for meeting those needs. This includes the use of health surveys and needs assessment, which should also focus on inequalities within economies, as well an informed approach to the most effective ways of tackling these needs. Health system benchmarks can be used to prioritize resource use and measure progress.

Recommendation: Support economies in taking an integrated approach to health care policy making. Policy makers should engage with all stakeholders in their health systems (including patients) about the level, allocation and use of resources for health care. Economies should consider how incentives and approaches to budget setting can support the best use of resources and encourage access to the most appropriate care and use of life science (and other) innovation.

Recommendation: Economies should recognize the role of primary health care (health care provided outside a hospital setting) including in prevention and treatment, as an efficient and accessible way of treating many patients and providing good access to life science innovation. This includes use of general practitioners (family doctors), pharmacists and other health care professionals. Resource allocation, budget setting and medical training need to reflect these priorities.

I. The Strategic Plan: Basic Principles

The inaugural Life Sciences Innovation Forum (LSIF I) developed a framework for the strategic plan based on the key elements of the life science value chain (Research, Development, Manufacturing and Marketing, and Health Services). A number of common themes emerged that were considered vital elements and basic principles of the plan. Member Economies agree that:

Policy makers should consider life sciences innovation oriented to the identified health needs of APEC member populations as an investment rather than a cost.

- Life sciences innovation is a critical area of growth and socio-economic development because healthy people produce healthy economies.
- Demonstrated productivity gains outweigh the costs of developing innovative products that address the health needs of the population.
- New product development and use can contribute to longevity, wellness and economic potential when linked to the health needs of the population.
- Sustainable health care policies are critical to realizing the value of life science innovation, and an informed approach to policy making that recognizes long term benefits of innovation is critical.

A successful life sciences industry requires political leadership and commitment from the top. Key areas of this commitment include:

- An integrated internal approach to health care policy making.
- An established process for inter-agency coordination on life sciences policy- and regulation-making among a broad range of government agencies including those responsible for Health, Science and Technology, Finance, Trade and Economic and Education
- Recognition of the importance of mechanisms to enhance innovation, such as public-private partnerships
- Consultation with key stakeholders: government, industry, academia and the community on priority setting
- Building human capacity through education and training
- Equitable, efficient and effective delivery of patient focused products and services
- Developing the necessary infrastructure to support life sciences innovation
- Policies that foster and reward innovation, and facilitate commercialization supporting health and economic benefits

The policy and regulatory environment most conducive to investment in life sciences innovation should be governed by the following basic principles:

- Transparency
- Efficiency
- Responsiveness and meaningful dialogue with all stakeholders
- Recognition of due process
- The priority health needs of the population
- Decisions based firmly on evidence of safety, efficacy and quality

Capacity Building and Human Capital Development will be critical to successful implementation

- Commitment to enhance life sciences programs in curricula at all levels of education
- Commitment to increase the pool of top quality scientists, regulatory policy experts and health services professionals; commitment to policies that foster, reward and encourage the retention and/or return of skilled professionals to the region
- Education mechanisms such as appropriate public-private sector partnerships to develop skills levels in each area of the life sciences value chain
- Collective programs to pool expertise and appropriate infrastructure
- Commitment to continuing medical and other professional education
- Programs for the continuing education of health professionals, including regulators
- Commitment to develop capacity building programs. The outcome of the APEC supported Life Sciences Readiness Assessment tool can serve as a guide for this purpose.

The cutting edge infrastructure necessary to support bio-medical life sciences innovation must be developed and maintained

- Verifiable and accurate top quality research, development, manufacturing and marketing and health services facilities meeting international standards that are supported by appropriate information technology platforms
- Centers of excellence
- Technology clusters
- A regional approach to critical infrastructure development

Harmonization of standards for life sciences products and services according to international best practices across all four segments of the value chain will give the APEC region a competitive edge and expand opportunities for the rapid development of innovation

- Agreement to harmonize quality standards for life science products and services according to international best practices (2003).
- Recognize the APEC principle that where there are existing international standards these will be the basis for harmonization in APEC and where appropriate international organizations exist for developing international standards, APEC economies will focus their coordinated efforts on promoting the development of international standards through these bodies.
- Efficient and robust clinical trial regulatory regime focused on safety, efficacy and ethical standards
- APEC LSIF “permanent representative” to the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH)
- International standards and best practices such as the Global Harmonization Task Force (GHTF) for devices, diagnostics and treatments

Collaboration and networking among APEC economies is important to assure efficiencies and that the region remains at the cutting edge of life sciences innovation

- Institutions specializing in life sciences innovation
- Funding institutions
- Health services institutions
- Networks such as the Asia-Pacific International Molecular Biology Network (AP-IMBN)
- Regional research initiatives such as the emerging molecular diagnostics initiative.
- Regional approach to existing and emerging diseases

Access to capital is a critical factor in determining the viability of life sciences innovation

- Venture Capital
- Seed funding
- Public-private partnerships
- Exploration of regional approaches to access to capital
- Government funding and multilateral development banks
- Foundations

Implementation of the Strategic Plan should include collective and Economy-specific actions

- Economy-specific implementation task forces including stakeholders
- Pathfinder approach as appropriate
- APEC-wide harmonization of standards for quality, safety and efficacy for life sciences products and services according to international best practices
- Human capital development
- Infrastructure development
- Access to capital
- Assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively

Economies are encouraged to identify investment, research and health policies that address the needs of all populations.

- Commitment to processes that support the identification of the health needs of all populations
- Commitment to policies that support the development and use of innovative products and services that provide the greatest health and economic benefits
- Budget setting and incentive structures that support the treatment of patients using appropriate interventions and in the most appropriate location of care
- Promote research that is responsive to the priorities of a sustainable health care system
- A sustainable approach to decision making, based around efficient and effective use of resources. This should recognize the value of primary-level health care, supported by treatment approaches that recognize the long term benefits of an intervention to patients, the health system and the economy.

II. The Strategic Plan: Goals, Operating Principles and Best Practices

Based on the outcomes of LSIF I (the basic principles) and agreements by Ministers and Leaders, this operational section of the strategic plan was developed from a matrix of goals and supporting operating principles, which was developed by the first Expert Working Group in Khon Kaen, reviewed by the Chair and Vice Chairs and reported to the LSIF Planning Group. The second Expert Working Group refined these goals and operating principles and developed best practices, where appropriate, that Economies should consider adopting, taking into account the rich diversity among and within Economies. The operational section was further reviewed by LSIF II, among other things to factor in recommendations for collective action going forward. Where possible, specific examples are given of successful models of cooperation, technology advances and implementation. So as to avoid duplication of effort, where possible principles, guidelines and best practices have been bench-marked against international best practices including those featured in the WHO, WTO, WIPO, GHTF and ICH, among others.

In terms of coverage, the goals, operating principles and best practices apply to all bio-medical life sciences products and services, including information technology platforms and supporting microtechnology, devices, diagnostics, medicines and treatments.

There is overlap and in some cases duplication in the goals, operating principles and best practices among the four areas of the life sciences innovation value chain. As one aspect of implementation will include economies determining their capacity building needs and prospects for economy specific or cooperative development, each segment of the value chain stands alone from that perspective and thus areas of overlap and duplication are maintained. Because significant interest was expressed by economies in the area of clinical trial regulation, this topic in the Development segment of the value chain has been substantially expanded to provide a best practices road map for developing capacity in clinical trials.

The following section of the strategic plan should be reflected in the LSIF Readiness Assessment Templates. As noted in the implementation schedule, interested economies are encouraged to conduct the readiness assessments as the first important step in implementing the strategic plan. Readiness assessments by interested economies should be completed by June 2005.

1. RESEARCH

Goals

- To promote high-quality research¹ in all areas of the life sciences value chain.
- To promote the sustainable application² of the outcomes of research.

Supporting Operating Principles³ and Best Practices

Policies, priorities and strategies

- Member economies should, individually and collectively, develop research policies, priorities and strategies that are:
 - Based on identified health priorities⁴ and economic objectives
 - Based on detailed policy research and evidence
 - Based on realistic assessment of research quality and capabilities
 - Subject to periodic reviews.
- *Best Practices*
 - Based on health and economic needs
 - Not duplicative
 - Capturing value through clearly defined outcomes
 - Consultative process involving all stakeholders
 - Inputs from international experts
 - Utilize best practice, peer review processes in the assessment of research
 - Regularly assess research practices and outcomes

Human capital and education

- Member economies should give priority to sufficient number of skilled researchers in life sciences.
 - The development of human capital should be pursued:
 - at all education levels
 - through collaboration among economies
 - through public and private collaborations
 - life sciences education curricula must include Good Laboratory Practice (GLP)

¹ All forms of research including basic, applied, and development research, in both public and private sectors

² Broadly defined as encouraging the many different forms of applications, e.g., more research, translation, commercialization, communication of research to the public, and use of the results in formulating government policy

³ In most, if not all, of these areas, capacity building will be of prime importance

⁴ Having regard to the existing burden of disease and emerging disease and vulnerable population groups

- *Best Practices*
 - Policies to encourage skilled professionals (including returnees)
 - infrastructure, remuneration, recognition and qualifications
 - Ensure appropriate mechanisms are in place to enable research to be conducted by qualified personnel
 - Strong life sciences curricula starting from primary level
 - Inter disciplinary approach
 - Cooperation among APEC economies through shared educational programs

Collaboration and networking

- Collaboration and networking are best achieved when based on trust, openness, complementarities, shared benefits and partnership
- Member economies should work together to:
 - Support research that leads to improved health outcomes
 - Encourage and facilitate collaboration and networks at all levels and between public and private sectors
 - Build on existing APEC networks in other APEC Working Groups such as the ISTWG, HRDWG, Health Task Force and networks such as the AP-IMBN
- *Best Practices*
 - Between economy-wide and international research funding agencies on specific priorities
 - High level commitment among collaborators

Infrastructure and coordination

- Member economies should, individually and together, work to:
 - Develop strong and viable organizations and other infrastructure to support research track
 - Establish centers of excellence with critical mass around research priorities
 - Provide adequate infrastructure to support research priorities
 - Encourage coordination between national research agencies
 - Develop mechanisms to align research activities on health priorities.

- *Best Practices*⁵
 - Technology platform for pharmacogenomics studies. Examples include Thailand's TCELS-Oracle
 - Technology platform for pre-clinical studies. Examples include Thailand's TCELS, MBC and Malaysia's Progenix
 - Establishment and accessibility of laboratories consistent with relevant international standards
 - Partners to provide technology and investment
 - Research to support health services. Examples include Thailand's TCELS, MBC
 - Strong and appropriate structure for clinical trials. Examples include Thailand's TCELS, MBC
 - Public contributions to support professional bodies
 - Information and resource exchange and networking. Examples include the European Molecular Biology Organization (EMBO)
 - Ensure constant quality standards of research facilities

Ethics and regulation

- Member economies should, individually and together, work to ensure:
 - Appropriate and transparent ethical frameworks for research on health
 - Appropriate and transparent regulatory frameworks for research on health
 - Appropriate systems and mechanisms to support good research practices according to international best practices
 - Adequate training of personnel in the regulatory and ethical frameworks
 - Protection and enforcement of intellectual property according to agreed upon multilateral standards and obligations (TRIPS).
- *Best Practices*
 - Clinical trials comply with international standards
 - Regulation of research is undertaken by qualified personnel
 - Recognition of diversity across economies
 - Harmonization of diversified practices is required (WHO's GTN)
 - TRIPs compliance

Financing of research

- Member economies should, individually and together, work to:
 - Determine and provide adequate financing of research on health priorities according to respective capabilities and other priorities
 - Encourage public-private partnerships in financing research on health priorities
 - Improve access to private funding for the application of research outcomes

⁵ Involves organizations, knowledge networks, and access to equipment, technology, and services

- *Best Practices*
 - Pooling of resources toward a common goal (GFATM, NHMRC/MRC/Wellcome)
 - Appropriate incentives to promote philanthropic initiatives
 - Appropriate incentives to create venture capital (such as Tax, Capital gains) as well as other forms of funding

Public awareness, confidence and support

- Member economies should, individually and collectively, work to
 - Communicate widely research policies, priorities, strategies and outcomes
 - Consult with and involve the community in research activities
 - Inform and consult the community on specific research issues
 - Consult with all stakeholders (government agencies, academia, industry, community) in the development of research priorities, policies, plans and implementation
- *Best Practices*
 - Public awareness portals (NIH website, Life Sciences Center in Newcastle-UK)

2. DEVELOPMENT

Goals and operating principles are listed below. The area of clinical trials has been selected as an example of a best practices approach to development and a roadmap is provided which has the potential to expand capacity, competence and expertise in conducting clinical trials throughout the 21 APEC economies. The area of clinical trials was chosen as a concrete example of an area where contributions to life sciences innovation may be established quickly and effectively, in accordance with Leaders' instructions. This approach can advance APEC's strategy to enhance public health and welfare through innovation in human health life sciences. In so doing, member economies should strive to create a supportive environment for clinical trials that encourages collaboration. among economies.

Goals

- Effective regulatory framework and infrastructure that ensures the safety, efficacy and quality of new products, while encouraging innovation.
- Partnership in working towards harmonizing regulatory practices and policies according to international best practices and standards
- Improved scientific and technical infrastructure
- Effective mechanism that promotes access to innovation

Supporting Operating Principles

Human Capital

- Member economies should work to encourage investment in collaborative research grant programs between APEC economies.
- Member economies should encourage collaborative public-private research grant programs to support the development of human capital in LSIF.
- Member economies should work to develop government/public sector core competencies
- Member economies should work to improve human capital stock through:
 - *Best Practices*
 - a clear implementable plan for continuous improvement of core competencies
 - Integration of life sciences as part of the school curriculum
 - Investment in domestic PhD and postdoctoral grant programs
 - Public Education & Awareness Programs

Organizational Infrastructure and coordination

- Member economies should establish a legal and regulatory framework incorporating interagency review of new policies, guidance and regulations
- Member economies should work to establish Centers of Excellence around research priorities
- Member economies will work to establish clinical trials registries, accessible to all interested parties

Physical Infrastructure

- Member economies will work to establish an IT structure that includes:
 - high speed grid computing networks
 - high performance computing capability
 - high speed telecommunications infrastructures that are based on open standards, which are secure, robust and facilitate real time collaboration between academic institutions, governments and the private sector
- Member economies will work to invest in adequate research facilities through mechanisms such as public-private partnerships

Environment for Investment in Research and Commercialization

- Member economies acknowledge the importance of adequate human, organizational and physical resources, including:
 - a transparent, predictable and science-based regulatory framework to enable the transition of basic research to applied science
 - mechanisms for commercial partnerships to enable transition from basic to applied research and commercialization
 - access to capital markets

Protection of Intellectual Property

- Member economies will work to implement a legal framework that is TRIPS compliant
- Member economies will work to provide adequate infrastructure and resources for enforcement of laws and regulations.
- *Best Practices*
 - Administrative and judicial frameworks that are fair, predictable, effective and efficient for concerned stakeholders
 - Intellectual property cases should be reviewed by appropriate judicial bodies with IP trained judges, evidence discovery frameworks, as well as mature injunction and bonding mechanisms to allow effective adjudication.

Legal and Regulatory Framework with Due Process

- Member economies will work to establish rule of law that includes an adequate mechanism for right of appeal
- Member economies will work to establish a transparent legal and regulatory framework that incorporates adequate notice and comment into regulatory development

Regulatory Framework: Sound Science

- Member economies will work to establish a regulatory framework that includes the following best practices:
- *Best Practices*
 - Includes assessment of current practice relative to international best practices (e.g., ICH, WHO, ISO, GHTF, ALPHA)
 - Provides a regulatory process based on safety, efficacy, and quality
 - use of public scientific advisory panels for specific scientific issues

Regulatory Framework: Transparency

- Member economies should establish a clear, published process for drug and device development regulatory review, that includes the following best practices:
- *Best Practices*
 - Clearly defined requirements for drug and device development process
 - Available through print and electronic media.
 - Mechanism for Industry Consultation
 - Mechanism for appeal

Regulatory Framework: Risk-and Evidence-based

- Member economies will work to implement clear, established data requirements consistent with international best practices
- *Best Practices*
 - Data requirements based on international standards (ICH, ISO, WHO), available through print and electronic media
 - Risk-based criteria with reference to safety, efficacy and quality for determining data requirements

Regulatory Framework: Predictability

- Member economies should establish published indicative timelines for regulatory processes and review of clinical data consistent with international best practices and regulatory guidelines

Good Clinical Practices

- Member economies will work to establish clinical trials requirements according to international standards
- Member economies will work to ensure adequate training of regulatory and clinical personnel, which may include:
 - The establishment and surveying of Independent Ethics Committees/ Institutional Review Boards (IECs)
- Member economies will work to release clear guidance to regulated community on clinical trial approval process

- *Best Practices*
 - Consider/adopt ICH GCP and WHO guidelines (when revision is completed) as a standard for clinical trials requirements

Good Manufacturing Practices

- Member economies will work to ensure:
 - The adequate training of government personnel, including inspectors
 - Assessment of current domestic practices in relation to international practice (e.g., WHO guidance)
 - Establishment of regulatory framework that recognizes manufacturers adhering to GMPs
 - Performance assessment criteria based on international best practices—adequate infrastructures , indicators and criteria for inspection at the level of the ICH/PICS

Environment for Capital Investment

- Member economies will work to ensure:
 - Effective and adequate IP protection defined as being TRIPS-compliant
 - Science-based, transparent, predictable, regulatory environment
 - Effective and adequate resources (human, organizational and physical)
 - Transparent market mechanisms including regulations
 - Mechanisms for public-private partnerships

Services Environment

- Member economies will work to establish a services environment that:
 - Has an inclusive, open and transparent process
 - Is supported by interagency involvement and coordination
 - Is consistent with GLP
 - Ethics committees/Independent Ethics Committees/Institutional Review Boards (IECs)
 - GLP/ISO 17025 Laboratory
 - OECD GLP Laboratory

A Best Practices Roadmap for Interested Economies for Clinical Trials: The Necessary Elements and steps.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. In addition to fulfilling the necessary elements of political leadership and regulatory system requirements indicated below, an economy wishing to establish GCP should be prepared to adopt and perform at the level of related internationally accepted standards including those expressed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, (ICH), the Pharmaceutical Inspection Cooperation Scheme, (PIC/S), the World Health Organization, (WHO) and the World Trade Organization, (WTO) as appropriate.

Tools are available to become acquainted with GCP and the related regulatory review, monitoring and inspection activities. For example, details on good clinical practice standards, procedures for audit and inspection of clinical trials (compliance programs) information to be included in a report of a clinical study conducted in human subjects, guidance to facilitate the mutual acceptance of clinical data by the regulatory authorities, dealing with the influence of ethnic factors and other clinical study –related guidance is available in ICH and other guidelines at <http://www.ich.org>. Also, see <http://www.who.int> and search GCP. Note that WHO GCP guidelines are undergoing revision. For information on the Pharmaceutical Inspection Cooperation Scheme, see <http://www.picscheme.org>.

Elements

Political leadership from the top.

A member economy in concert with industry, academia and others as appropriate will develop a coordinated strategy to promote life sciences innovation. The commitment to achieve and sustain Good Clinical Practices requires maintaining an environment that attracts investment, developing and applying legislation that is consistent with international standards, establishing public advisory boards and ensuring the provision of adequate financial and skilled human resources and facilities subject to monitoring, audit and avoidance of conflict of interest.

Regulatory system requirements

An adequately staffed healthcare infrastructure that includes a science-based regulatory system characterized by transparency, consistency, predictability and effectiveness that protects health while encouraging investment in innovation is essential. The staff should possess the regulatory review capacity to interpret reports of clinical trials and the skill set required to deal with human subject protection, and to conduct the inspection, auditing and monitoring required to assure GCP facility adequacy and practitioner capability to carry out clinical trials at an internationally acceptable level.

Roadmap Overview—Individual & Collective Actions

- Readiness Assessment—Facilitated identification of capabilities and/or needs
- Evaluate current practice relative to international best practices (e.g., ICH E6 or revised WHO GCP)
- Develop common understanding of Regulatory Principles. Clinical trials principles: from regulatory authorization to GCP implementation
- Set priorities within APEC and within individual economies
- Establish a step by step, harmonization process for consensus building within APEC under the auspices of LSIF e.g.,
 - Agreement on principles for clinical studies
 - Common clinical trials application (CTA) format and content
- Coordinated program for “training the trainers” (regulatory agencies) within APEC—common curriculum
 - APEC economies share best practices
 - Develop training programs in each economy
- Form Technical Working Groups to advance objectives faster—creative use of technology to progress work program (e.g., videoconference, web cast)

Economy step-by-step implementation

Step 1:

Readiness Assessment—Economies willing to make the commitment necessary to achieve and sustain GCP should identify themselves. The initial step of an implementation plan for achieving GCP is an assessment of the capabilities, needs and willingness of an economy to achieve and sustain performance of both regulatory activities and clinical activities in conformance with internationally accepted standards. The assessment facilitators will review the economy’s coordinated strategy to achieve and sustain GCP and will evaluate current practice in the regulatory system and by clinical trial practitioners relative to international best practices (e.g., ICH E6 or the revised WHO GCP). The assessment summary will include recommendations for next steps.

Step 2:

Based on recommendations from the Step 1 assessment, a training curriculum will be developed to ensure a common understanding of principles related to regulatory and clinical trial activities. Participants in training should include regulatory officials, individuals who may comprise an advisory board on GCP’s, and clinical trial practitioners. The curriculum will be applied as part of a coordinated program to “train the trainers” so that APEC economies will have the ability to conduct additional training, to share best practices and to form technical working groups to advance objectives faster. Use of technology such as videoconferences, webcasts and web-based training tools will be useful for Step 2 activities.

Step 3:

Based on recommendations from the Step 1 assessment, with assistance from other APEC economies as needed, in a transparent manner, leaders of APEC economies will develop and enact legislation and guidance related to GCP and carry out other strategies designed to strengthen, manage and maintain GCP’s.

Step 4:

APEC economies continue to share best practices, perform monitoring and self-audits and obtain training as needed to ensure that both their regulatory system and clinical trial practitioners maintain the competence to perform in conformance with international standards. Based on certain indicators of success such as, but not limited to, the sample metric below, APEC economies may report on their progress at APEC LSIF meetings.

Some Indicators of Success

An attractive environment for innovation in life sciences can be measured qualitatively and quantitatively to show progress toward meeting the goals, for example through:

1. The number and sites for clinical trials should increase.
2. The types of trials should be reflective of the innovation an economy wants to attract, e.g., more multinational than local trials, trials for products/indications important to advancing the public health of the particular APEC economy.
3. Increased numbers of patients recruited to studies
4. Increased number of applications and approvals for clinical trials.
5. The review timeline should shorten.
6. Increased level of compliance to regulatory requirements /best practices

Example of a Metrics Chart

- Number of trials and/or sites
- Type of trials: Multinational vs. local / Phase I, II, or III /Bioequivalence
- Patient recruitment
- Number of applications
- Number of approvals
- Review timelines
- Level of compliance to Regulatory requirements / Best Practices

3. MANUFACTURING AND MARKETING

Goals

- To ensure a transparent and science-based regulatory framework for the manufacturing and marketing of innovative life sciences products that will assure the safety, quality and efficacy of the products.
- To ensure the ability of patients to have timely and effective access to appropriate innovative products.

Supporting Operating Principles and Best Practices

Transparent Regulatory Framework

- Member economies will work to establish a legal framework that incorporates adequate notice and comment into regulatory development:
 - Actual time-frame must be reflective of extent and impact of proposal and provide all parties with ample time for analysis of proposal and preparation of responses.
 - An adequate mechanism for right of appeal
 - Sponsor access to regulatory findings, especially in case of negative findings
 - An open and transparent process without risk of abuse to the regulatory authority, with adequate information to support its findings without being subject to repeated rounds of questioning on the same topic
 - The opportunity to input with the expectation of being heard
- Member economies will work to adopt the principles of due process in their regulatory framework
- *Best Practices*
 - Notice of regulatory development made to all stakeholders (patients, regulators, industry)
 - Notice includes description of contemplated regulation
 - Public rationale provided for the decisions surrounding the proposed regulatory development
 - Framework for due process that includes access to regulatory findings, the right of recourse, and a mechanism for stakeholders to consult with regulators
 - All parties agree on comment period according to a published process.
 - Mechanism for fast-track review of important new life-sciences products

Science-Driven Decisions

- Member economies will work to implement a science-based regulatory framework where decisions are made firmly on the basis of safety, efficacy and quality and equal treatment is provided to foreign and domestic applicants.
 - Framework should contain predictability and published timeframes for regulatory processes
- *Best Practices*

- Regulatory framework emulates appropriate international standards and international best practices such as ICH, WHO, ISO, and other international bodies working toward harmonization such as the Global Harmonization Task Force (GHTF) for devices.
- Takes into account on-going developments in the quality area for pharmaceuticals, devices and other health care products (including ICH guidelines Q8, Pharmaceutical Development and Q9, Risk Management currently under development, device (GHTF) and diagnostics standards)
 - Allows for further developments in the area of quality management beyond the cited ICH guidelines.
- A clear and published process for life sciences products and services development and regulatory review, a mechanism for industry to consult with regulatory authorities, and a mechanism for appeal
- Consistent application of standards leading to predictable outcomes
- Decisions based on the data presented (not on who is presenting the data) and independent of the individual reviewer or the inspector making the decision
- Use of public scientific advisory panels for specific scientific issues related to a marketing application, new technology, or new regulatory initiatives

Capable and Sufficient Human Resources

- Member economies will work to create an infrastructure supporting all levels of education
- Member economies will encourage investment in collaborative research grant programs between APEC economies that:
 - may be used to support investigations into both technology and policy; and
- Member economies will work to establish collaborative public-private research grant programs to support the development of human capital in LSIF.
- Member economies will work to encourage human resource development in the private sector; that is, continuing education for employees, that:
 - provides an opportunity for partnerships involving professional societies that are already established in the APEC economies
 - may lead to the establishment of an APEC-wide federation of those professional societies that support the life sciences industry in a region
- *Best Practices*
 - Collaborative research grant programs based on the model established by the World Health Organization (WHO)
 - Apparent mechanisms for continuing education that allow domestic and international professional societies to have a role
 - Centers of excellence
 - Public-private research collaborations
 - Promotion of exchange of people and ideas

Adherence to Good Manufacturing Practices (GMP)

- Member economies will work to adopt an international baseline guidance for interpreting Good Manufacturing Practice (GMP).
 - Adherence to baseline good manufacturing practice should be acceptable in most cases
- Member economies will work to establish a regulatory framework that recognizes manufacturers that comply with GMP:
 - Performance based on international best practices
 - PICS (Pharmaceutical Inspection Cooperation Scheme) as a mechanism for training, documentation and information exchange across APEC economies at the bilateral and/or multilateral level.
- Member economies will, individually and together, work to provide adequate training of government personnel, with the same training to be delivered to inspectors and industry personnel
 - Training design should take into account both current domestic practices and international best practices
- *Best Practices*
 - Commitment to reviewable, contemporary quality systems such as ICH Q7A, WHO, PICS, 21 CFR 210-211, and applicable EMEA standards
 - Cooperative activities, for example through PICS extended to all APEC economies

Respect for Intellectual Property Rights

- Member economies will implement a legal framework for patent protection, adequate infrastructure, and resources for enforcement of laws and regulations in order to protect intellectual property.
 - Mechanism that provides for the enforcement of those rights
 - Mechanism for public notice of submission prior to approval
 - Information (including notice of marketing applications to holders of patents if a product is to appear on the market during the patent life of the original product) should be available and accessible to the holder of intellectual property rights, government agencies, and potential infringers
 - APEC-wide enactment of WTO-TRIPS by all member economies with adequate and effective enforcement of IPR, chance of apprehension, and criminal prosecution of counterfeiters across the region (such as based on the WHO guidelines for the development of measures to combat counterfeit medicines).
 - Acceptance of intellectual property rights must be consistent with WTO membership commitments.

- *Best Practices*
 - Enactment of laws consistent with WTO-TRIPS
 - Enforcement of those laws and regulations, including those laws against counterfeiting;
 - Cooperation among economies to combat counterfeiting
 - Marketing approvals should not lead to the infringement of intellectual property rights

Access to markets

- Member economies are encouraged to create an environment where there is adequate and timely access to markets for manufacturers and effective access for users in accordance with public health priorities.
- *Best Practices*
 - Market policies that reward innovation and maximize health benefits to society
 - Ability to discuss off-label uses with medical experts
 - In the spirit of scientific exchange
 - Consideration given to establishing a framework by regulators in an economy, where appropriate
 - Ability to communicate with consumers using balanced, ethical and good quality information and conduits

Physical Infrastructure

- Member economies will work to develop adequate information technology infrastructure that ensures the ability for regulators to communicate across economies
- *Best Practices*
 - high speed grid computing networks
 - high performance computing capability
 - high speed telecommunications infrastructures that are based on open standards are secure, robust and facilitate real time collaboration between academic institutions, governments and the private sector.

Environment for Investment in Research

- Member economies should establish a transparent, predictable, and science-based regulatory framework to enable the products of basic research to transition into use for applied science as one of the most important operating principles
- Access to capital markets likewise is a necessity for an APEC economy to implement successful manufacturing and marketing capacity

Environment for Capital Investment

- To attract investment Member Economies will need to implement a science-based, transparent, and predictable regulatory environment that provides protection of intellectual property in order to encourage adequate capital investment

4. HEALTH SERVICES⁶

Goals

- To create an environment that supports social and economic goals related to life sciences innovation
- To foster an inclusive, integrated, and sustainable approach to policymaking and implementation (policymakers need to co-ordinate their activities and consult with stakeholders)
- To monitor the quality and performance of health systems to ensure appropriate use of innovations
- To advocate accessibility, affordability, sustainability, and value from innovation in health services

Supporting Operating Principles and Best Practices

Human capital and education

- Member economies should make necessary investments in human capital to ensure that economy is able to collaborate and lead research activities.
- Investments may include cross-country collaboration and public-private partnerships
- Within the economy, members will educate their science base to ensure appropriate utilization of innovations

Organizational infrastructure and co-ordination

- Member economies will measure and assure the quality of health services and research infrastructure

Physical Infrastructure

- Infrastructure is a key component of ensuring health systems create an environment that is conducive to the development and use of innovations. In particular, ensuring that different parts of the health system can “talk” to one another and that use of innovations, their impact, value and quality can be monitored is important. Member economies will invest in IT systems and infrastructure to ensure this is so.

⁶ Endorsement and implementation of this section is subject to constitutional power in respect of health services residing at the federal level of government, and is without prejudice to member economies’ division of responsibilities between central and local authorities or agencies of government.

- *Best Practices*
 - IT systems that are coordinated, with interoperability and common standards across the health system
 - transparent and efficient tendering is used to procure IT infrastructure
 - There are feedback mechanisms to ensure objectives are being met and quality standards enforced

Protection of intellectual property

- Member economies will commit to ensuring a legal and regulatory framework to guarantee IP standards is in place and enforced. The Health Services Group endorses the recommendations made by others in this respect, with the additional recommendation that mechanisms should be in place to discourage the prescribing or use of counterfeit products in clinical practice.
- *Best Practices*
 - Continuing public and physician education to promote awareness of the harmful effects of counterfeits
 - Reimbursement mechanisms that do not reward the use of counterfeits (e.g. there are cases where a cheap counterfeit is dispensed, yet reimbursement is sought at full cost)

Transparent regulatory framework

- Member economies are encouraged to:
 - Implement a transparent, timely and consistent framework for governing reimbursement decisions
 - Monitor the time from authorization to reimbursement decision
- *Best Practices*
 - Member economies are encouraged to:
 - Institute a clear and efficient process for public reimbursement decisions
 - Institute a transparent, objective, and science-based reimbursement decision-making process
 - Provide an opportunity for innovator and clinical experts to have input into the reimbursement decision-making process
 - Where there is a governmental reimbursement process, have government retain overall control over specific reimbursement decisions, on advice from an independent body as appropriate, but there is clarity over who makes which decisions/recommendations.
 - Allow products to be available privately as soon as they have marketing authorization, with consideration for public reimbursement via a clear and consistent process

Good clinical practices

- Member economies are encouraged to work towards health systems with well-trained regulatory and clinical personnel who have clear guidance over processes. Ensuring quality of innovations is an important part of this process.
- *Best Practices*
 - There should be mechanisms for reporting adverse events related to the use of innovations, which should be collated and considered centrally.
 - Regulatory responses to data on adverse events should be driven by regulators and not politicians, with an emphasis on ensuring decisions are proportionate to the risks.

Empowered Patients

- Member economies will take proactive steps to ensure patients have access to comprehensive information so that they can make balanced judgments about when and how to access health care.
 - Patients should have the opportunity to be involved in decisions about disease management, choice of treatment, and use of innovations
- *Best Practices*
 - There should be mechanisms that provide easily accessible, accurate, fact-based, unbiased, and comprehensive information to patients (e.g. internet, patient information leaflets)
 - Innovators should make information publicly available to consumers and patients about medicines while respecting the regulatory requirements and the ethical principles that govern this type of relationship

Evidence-based medicine

- Noting that evidence-based medicine can be defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients, and that the practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research, Member economies are encouraged to:
 - create strong communication channels between physicians, government, patients, and innovators to report adverse events and to understand the use of products in a real clinical setting
 - apply evidence-based medicine consistently across the health system, to the full range of interventions.
 - allow for clinical guidance based on robust evidence
 - promote accountability of all parties in the distribution chain by clarifying their roles and responsibilities
 - Promote guidance, which enables clinical freedoms
 - ensure physician knowledge is continually updated about the benefits of new innovations
- As a general principle, cooperation across APEC economies to develop and co-ordinate the application of evidence-based medicine is recommended
- *Best Practices*
 - Information about adverse events must be assessed by the government, regulatory review bodies and independent health experts in a fair and balanced manner
 - Evidence-based medicine should be applied to all products and health care interventions
 - Evidence-based medicine should be considered a valuable tool for informing clinical decisions
 - Physicians should be engaged in continuing medical education.
 - There should be ongoing review of evidence-based guidance
 - Procedures should be in place for collecting information on the use of innovations in practice

Efficient use of resources

- Member economies are encouraged to:
 - Take an holistic approach to how they decide on the level of resource flowing into health care and on how it is allocated
 - Assess the health care needs of local populations, which should in turn inform decisions about the level of resources flowing in to health care
 - In conjunction with stakeholders, identify the specific needs of vulnerable populations and how these might be addressed in a fair and equitable manner
 - Have resource allocation reflect all these needs, which should include a national dialogue to understand the priorities of the population as well as local flexibilities
 - Take a long-term focus to allocating resources. This includes supporting preventative medicines and healthy lifestyles. It also includes a consistent approach to budget and priority setting over time

- Use health targets to help prioritize resource use. These targets must reflect the needs of the population and be based on sound evidence about what interventions work effectively
- Make incentive structures compatible with ensuring that physicians base their decisions around the clinical needs of the patient taking account of the resource constraints of the health system. This includes physicians taking a long-term view to treatment options, and recognizing that expenditure in one part of the system (e.g. primary care) can often generate savings in another (e.g. secondary care)
- Avoid setting budgets in a compartmentalized way (e.g. keeping prescribing budgets totally separate from other primary care budgets and secondary care budgets)
- Note that compartmentalized budget setting may be harmful for health services innovations in that:
 - A risk exists that physicians in one part of a health system are reluctant to use an efficient innovation because it imposes a cost on their budget but the savings are realized elsewhere or many years in the future
 - An innovation that is efficient from the health system perspective may be under-used because individual physicians do not see their budgets or the benefits from the perspective of the whole system
- *Best Practices*
 - Regular survey and other exercises to understand the underlying disease burden and its distribution in the population and prioritize health needs, and to understand the priorities of citizens
 - Resource allocation processes that reflect these needs (e.g. there should be a planning process for allocating resources to the right parts of the health system to maximize health benefits, given the needs identified)
 - Programs that emphasize health promotion and disease prevention. These should be focused both on encouraging citizens to live healthier lives and on ensuring physicians have good incentives, with support and incentives to detect and treat illness at an early stage
 - A well-developed primary care system, with holistic approaches to health teams (and hospital) reimbursement, that are consistent with managing patients outside the hospital setting where this is efficient and in the interests of patients. This includes making good use of all health professionals.
 - Targets can help to meet some of these objectives, but where used they should not be an over-riding constraint that distorts decision-making

Prescribing Behavior

- Member economies are encouraged to ensure prescribing decisions are based around clinical needs to maximize the health and well-being of the population

- *Best Practices*
 - Separation of prescribing from dispensing
 - Remove financial incentives from prescribing decisions
 - Fees/physician reimbursement should be consistent with goals of effective resource use (see above), particularly in terms of the incentives they imply
 - Reimbursement mechanisms should be consistent with ensuring patients have good access to medicines and that prescribers have incentives to use them appropriately.

Use of traditional remedies

- Member economies will, where evidence shows sound clinical and efficiency benefits, work to make appropriate use of all types of health intervention, whether modern or traditional

Quality assurance programs

- Member economies are encouraged to work towards the mutual acknowledgement of quality assurance systems, such as hospital accreditation systems
- Member economies should be encouraged to move towards common standards
- *Best Practices*
 - National programs for the external evaluation of health care, with incentives to encourage continuous improvement of safety and quality of health care
 - Feedback to encourage dissemination of good practices

III. Conclusions and Recommendations for Collective Action Going Forward

Conclusions

Implementation of the basic principles of the strategic plan will provide benefits to health and well being by creating an environment conducive to promoting global trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation according to Ministers' and Leaders' instructions. Ensuring that economies work towards harmonizing standards for life sciences products and services, and that resource needs are addressed, will allow the region to assume a global leadership role in this sector. An integrated, multi-disciplinary approach to policy-making involving all stakeholders is critical to success.

Implementation by economies of the basic principles and the goals, operating principles and best practices in the strategic plan will help accelerate the processes of risk detection, prevention and cure of the communicable and life-style diseases that afflict the people of the region. These goals, operating principles and best practices have been selected to attract top quality investment in targeted products and services that will meet the health and economic needs of the region and serve as a global model of cooperation to address pressing health policy issues, including the needs of vulnerable populations. In addition the goals, operating principles and best practices for each of the four areas of the value chain have been developed to ensure that investments made in every stage of the health care process by governments, industry and academia are more effective, including primary prevention against diseases risks and focusing on most vulnerable populations in accordance with Leaders' instructions.

Implementation of the Life Sciences Innovation Readiness Assessments will allow interested member economies to identify where to place their resources most effectively and efficiently and define their capacity building needs in accordance with Ministers and Leaders instructions.

The region has a clear comparative advantage in life sciences research, development and health services. But competencies and resources are not spread evenly. The area of clinical trials has significant potential for further development given the rich diversity of the region. A roadmap to build capacity and competence in clinical trials is provided as an example of where contributions to life sciences innovation can be established quickly and effectively according to Ministers' and Leaders' instructions. Building partnerships to harmonize clinical trial regulations and practices according to international best practices will be critical to success.

There is room for significant enhancement of research capabilities through collaboration, networking, pooling resources, and examining the prospect of cooperative funding initiatives.

Ministers recognized that there was a need to improve manufacturing and marketing standards and consistency throughout the region. Thus they agreed in principle to harmonize quality standards for life sciences products and services according to international best practices. The strategic plan provides a best practices approach to implement that commitment.

Health services is an area where some economies in the region are rapidly developing world class systems. But there is room for substantial improvement. Health services accreditation systems according to international best practices are to be encouraged in the region to promote the highest quality care for patients. But this is only one part of the process. Access to innovation needs to be strong for their benefits to be realized, which needs to be supported by transparent and efficient regulatory and budgetary processes. Approaches to priority setting and the allocation of resources also needs to be sufficiently flexible to address emerging disease problems.

There is potential for a broader effort at harmonization in the life sciences area through collaboration with relevant international standards bodies and initiatives, which would address the harmonization of regulatory standards and practices for life sciences products and services.

Recommendations for Collective Action Going Forward

Access to capital was identified as a key factor in supporting the development of innovative products and services in the region. Among other things, it is a determinant on whether an innovation can be developed and brought to the consumer efficiently and effectively.

Recommendations

1. Instruct officials in interested APEC economies and the private sector to jointly explore the prospect of establishing a Regional Venture Capital facility directed at accelerating devices, diagnostics, medicines and other treatments for the diseases of the developing economies, and at emerging prospects from developing member economies.
 - In consultation with the Technical Working Group of the Finance Ministers process establish a taskforce of experts to develop options for consideration by economies individually and collectively.
2. Establish a Task Force of experts including medical research funding bodies to examine the feasibility of establishing a Cooperative Program between National Health Research Funding Bodies to identify and fund high quality research in member economies. The Task Force should:
 - Report its findings back to appropriate Ministers.
 - Draw on experience in cooperative programs of the national research funding bodies such as the National Institute of Health in USA, the National Health and Medical Research Council (NHMRC) in Australia and comparable bodies in other economies.
 - Programs should be focused on:
 - Research on health issues particularly relevant to developing economies but not being adequately resourced such as dengue fever, malaria.
 - Areas of particular promise in developing member economies and/or on cooperative programs that bring together researchers from several economies.
 - Leveraging programs such as the REDI, the cooperative US-Singapore facility for training and response to emerging diseases in the region
 - Funding options include:
 - Member governments
 - Private grant funding (e.g. Wellcome, other foundations)
3. Explore best practices for fiscal incentives to attract R&D, manufacturing and commercial operations into the region consistent with existing international obligations

It is widely recognized that **education and human capital development** in the life sciences is critical. Education is increasingly becoming traded internationally, but a cooperative program within APEC focused on the life sciences could accelerate this process in relevant areas. This issue keeps recurring, and is certainly worth further detailed investigation as a major potential outcome from the Forum.

Recommendations

4. Encourage APEC Education, Health, and Science and Technology Ministers to give appropriate priority to life sciences education and continuing medical professional education and training as described in the strategic plan.
5. Encourage APEC members to develop and implement through appropriate training, region-wide life sciences curricula at all education levels. Encourage exchange programs on life sciences among APEC economies at secondary and tertiary levels. In doing so develop coordinated post-doctoral fellowship programs dedicated to life sciences.
6. Encourage programs for continuing education of all health professionals, including regulators.
7. Without duplicating other organizations, encourage the establishment of a federation of regional professional societies that may in turn be recognized by international professional societies.
8. Encourage the development of patient information and education such as disease awareness programs and information on the full range of treatment and management options for important disease areas, (including, for instance, dietary and lifestyle advice, as well as self-care).

Some facilities for the development of biomedical products from the R&D stage (e.g. toxicology, protein production) may be beyond the capacity of an individual economy but can be effectively provided on a regional basis. **Cooperative development of regional biotechnology and supporting information technology infrastructure** consistent with relevant international standards, including contract research organizations (CRO's) and contract manufacturing organizations (CMO's) could be an efficient way of pooling resources in the region.

Recommendations

9. Building on current initiatives in APEC member economies, examine the feasibility and prospect of interested economies establishing a regional Molecular Biology Laboratory (drawing on the model of the European Molecular Biology Laboratory)
10. Consider the prospect of other regional facilities such as chemical pilot and production plants and analytical facilities.

11. Direct the Life Sciences Innovation Forum to commission a study of the potential for cooperative development of innovation and applications platforms for the life sciences that includes but is not restricted to IT and related platforms, and advanced genomic and proteomic infrastructure. The study should include an examination of real needs of member economies and how they might be met by a cooperative program.

Harmonization of standards for life sciences products and services (Appendix X provides an indicative list) was recognized as a critical element in all areas of the life sciences value chain and a basic principle going forward. To maximize the region's ability to address the region's health needs in the four areas of the value chain, policies, standards and regulatory mechanisms should be reviewed against international best practices, in accordance with APEC principles on harmonization.

Recommendations

12. Noting that APEC LSIF has permanent representation on the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH) and that APEC member economies also participate in other Life Sciences standards bodies such as the Global Harmonized Task Force for medical devices, APEC Leaders agree in principle to move toward a regional harmonization process amongst APEC economies with a view to achieving close collaboration, consistency with relevant international standards and global best practices through collaboration with bodies such as the GHTF, the Agenda for Leadership Program and Health Care Accreditation (ALPHA) and the ICH GCG and instruct LSIF to develop a roadmap to achieve this goal for life sciences products and for services.
13. Instruct the Forum to develop a mechanism for reviewing progress and the harmonization of standards against international best practices.
14. Encourage programs for information sharing among regulators with regard to safety issues, counterfeit products and other risks

Building on the strategic plan, cooperative projects are underway to develop the necessary innovations to address early **detection and prevention of diseases** in the region. For example, an independently supported Pacific Health Summit will be held in June 2005 to focus on new technologies in early detection and prevention of diseases and policies to support these emerging technologies. The APEC Health Task Force also is addressing health priorities including health security threats in the region, and independent initiatives are being promoted by major research organizations in the region

Recommendations

15. APEC Leaders welcome the launching of a series of independently supported Pacific Health Summits beginning in June 2005 involving stakeholders in the early detection and prevention of diseases in the region and discussion of policies to support associated emerging technologies. LSIF to consider representation at this Summit.

16. Where appropriate, cooperative programs should be conducted in coordination with the APEC Health Taskforce.
17. APEC Leaders to note that a number of APEC member economies have expressed interest in participating in a major molecular diagnostics initiative to help reveal the early onset of chronic diseases and an associated large scale cohort and monitoring program to gather essential information for the assessment of risk and early disease intervention.

Implementation Schedule

Some APEC member economies may choose to move more quickly than others in terms of implementing the strategic plan consistent with APEC's flexible, voluntary and consensus-oriented approach. For member economies choosing to move quickly to implement the strategic plan, the following implementation schedule is provided for endorsement by Ministers and Leaders:

January, 2005

(i) Intersessional review and revision of Life Sciences Readiness Assessment template by LSIF Drafting Group.

February, 2005:

(i) Develop a budget and associated criteria for APEC support for economy-specific Life Sciences Readiness Assessments.

(ii) Outreach to other APEC groups, including the ISTWG, HRDWG, Health Task Force, Finance Ministers TWG.

April 2005:

1st meeting of the Ad Hoc Technical Working Group on Life Sciences Readiness Assessments.

Objectives:

- review and refine the readiness assessment templates to be consistent with strategic plan best practices guidelines;
- develop guidance for economies and facilitators.

April/May 2005:

(i) Launch economy specific readiness assessments.

(ii) Ministerial-level meeting. Objectives: review examples of best practices of a holistic approach to life sciences innovation to ensure that resource levels and allocations maximize the return on investment in terms of economic and health benefits; discuss ways of outreach to stakeholders, including within governments, academia, industry and the community.

June 2005:

(i) Member economies factor the basic principles of the strategic plan into their policy-making infrastructure going forward.

(ii) Possible LSIF representation at the Pacific Health Summit on early detection and disease prevention

July 2005:

(i) Completion of readiness assessments by those economies who wish to develop a specific area of the value chain and/or undertake actions to stimulate the availability of innovative products and services.

(ii) Complete first draft of ways to implement collective actions and recommendations going forward for presentation to Ministers, including priority areas.

(iii) Economies finalize economy specific and collective milestones for implementation.

August, 2005:

(i) Submission of statements of intent and capacity building needs.

September, 2005:

(i) Presentation of progress to LSIF III and finalization of implementation steps going forward

November, 2005:

(i) Progress report to Ministers and Leaders/Recommendations for implementation of priority collective actions going forward, including any relevant outcomes from the Pacific Health Summit.

Appendices

- I Terms of Reference
- II Report of the Inaugural Life Sciences Innovation Forum: August 14-15, 2003, Phuket, Thailand
- III Report of the 2nd Life Sciences Innovation Forum: September 16-17, Penang, Malaysia
- IV Reports to the Life Sciences Innovation Planning Group
- V Goals, operating principles and best practices: Report of the Expert Working Groups
- VI Example of draft LSIF Readiness Assessment Template: substance of template awaits endorsement of the strategic plan
- VII Report of the LSIF Permanent Representative to the ICH GCG
- VIII Officers of the Life Sciences Forum and Expert Working Groups
- IX Glossary of Terms
- X Harmonization Initiatives
- XI Extracts from Ministerial and Leaders Statements concerning Life Sciences Innovation

**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 life-sciences 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”.

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

⁴ 2003/SOM1/CTI/025

life-sciences innovation in the region and will not duplicate current and ongoing efforts of other APEC fora.

2.2. Based on these discussions, the Forum will develop 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. For the purpose of this Forum, 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 economic and technical cooperation, including capacity building, and 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 be held annually, with the inaugural meeting in August 2003. 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, the LSIF may consult with other APEC specialty fora, including the APEC Industrial Science and Technology Working Group (ISTWG), the APEC Business Advisory Council (ABAC), and international and regional fora as appropriate. The work program and outcomes may also be conveyed to the ISTWG, the ABAC and other relevant APEC fora. Using the APEC reporting structure, through the CTI, to Senior Officials, and Ministers and Leaders when appropriate, progress towards the identification of critical issues in the life-sciences value chain and recommendations to address these will be reviewed annually. The LSIF terms of reference will be reviewed in 2006.

3.2. The Forum will be supported at the working level by an ad hoc Planning Group, comprising interested representatives from the private sector, academia and government officials. The ad hoc Planning Group will meet as needed before the Forum to determine the scope and operational structure of the Forum, 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.

3.3. The annual Forum will involve appropriate senior representatives of the life-sciences/human health sector and of APEC member economies as mandated by Leaders.

4. Administration of the Forum

4.1. The Forum will be managed by a Chair and two Vice-Chairs representing the life-sciences industry, academia and the public sector. The Chair and Vice-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 up to two years.

4.2. A Coordinator for the Forum will be identified to disseminate information, Chair Planning Group meetings, and coordinate with the APEC Secretariat, ISTWG, ABAC, appropriate APEC Sub-Committees, other Working Groups and Experts Groups, and international bodies as appropriate and as identified by the Forum.

4.3. To facilitate the work of the Chair and Vice-Chairs 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.

4.4. The names of the Chair and Vice-Chairs and contact details will be deposited with the APEC Secretariat by the Forum coordinator.

Key Outcomes – Life Sciences Innovation Forum **14-15 August 2003**

The inaugural meeting of the APEC Life Sciences Innovation Forum (LSIF) was held August 14-15 in Phuket Thailand chaired by H.E. Suwit Khunkitti, Deputy Prime Minister, Thailand. Over 200 participants drawn from academia, government and industry discussed implementation of the APEC Leaders instructions to develop a strategic plan for Life Sciences innovation in the region. Several key themes emerged that were considered vital elements of a framework for the plan.

Life Sciences innovation was recognized as a critical area of growth and socio-economic development--healthy people produce healthy economies. Productivity gains far outweigh the costs of developing innovative products. New product development and use adds significantly to longevity, wellness and economic potential.

Successful Life Sciences industry requires political leadership and commitment from the top and depends on the proper policy environment, public-private partnership, human capacity, and efficient and effective delivery of patient focused products and services. Guiding principles moving forward must include transparency, meaningful dialogue with stakeholders and recognition of due process. Capacity building will be critical to successful implementation.

Because life sciences technology is fast moving it was recommended that the strategic plan be finalized by the time of the APEC Leaders Summit in 2004. It also was recommended that expert groups work intersessionally to develop a road map encompassing best practices for each of the four main segments of the life sciences innovation value chain: research; development; manufacturing and marketing and health services for endorsement by Leaders at their 2004 Summit.

A number of immediate outcomes were identified as recommendations for Leaders endorsement at their October 20-21 meeting in Bangkok including: agreement in principle to harmonize quality standards for life sciences products and services according to international best practices; and, an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

Elements of the Framework for the Life Sciences Innovation Strategic Plan

LSIF recommended the following key elements for inclusion in the framework for the Life Sciences Innovation strategic plan.

1. Research

Objective 1: Promote quality scientific research

- Physical & Intellectual infrastructure
- Human capital – brain train not drain

- Integration into international & APEC Networks
- Research priorities –economy specialization, disease specific
- Centers of Excellence
- Realistic assessment of capabilities
- Efficient use of research_funding – research audits for quality outcome
- Tech transfer groups

Objective 2: Translational Research

- Commercially viability
- Patient focus
- GMP-based CMOs
- Rewards for institution and scientists
- Collaboration

Objective 3: Commercialization

- IP
- Environment and structure for commercial partnerships (NIH-type structure)
- Business development unit – Alliances, Spin offs
- Technology transfer
- International competitiveness
- Incubation centers
- Capital – seed funding

Objective 4: Investment in Education & Training

- Education structure – life science in primary school curriculum
- Awareness/Communication with public and financial institutions
- Training

Recommendations to APEC Leaders

- Make life science a priority and commitment
- Increase R&D funding
- Efficient and consistent policy environment
- Inter- governmental collaborations and networks
- Create APEC ‘APMBL’
- Attract private equity institutions and pharmas

2. Development

Regulatory Practices Supporting Innovation

- Transparency
- Efficiency
- Flexibility
- Responsiveness
- Protects IP
- Efficient & Robust Clinical Trial Regulation

HARMONIZATION

- To expand opportunities for rapid development of innovative medicines
- Example of ICH as success in Harmonization
- Harmonization, not “homogenization”
- ICH “Mickey Mouse” model
- Move to globalize ICH activities through ICH GCG
- Clinical Trials
- Opportunities in Asia – Large patient base, unique and unmet medical needs, large pool of professionals, IT infrastructure
- Challenges –
- Varied social systems, cultures, traditions
- Different regulations, processes – new & existing
- Insufficient GCP training
- Possible players to Unify standards – Charitable research organizations, APEC

- **APEC - Development**
- Different levels of development of regulations in economies across APEC
- Possible groupings within APEC based on similar standards and needs – e.g. Korea, Chinese Taipei and Japan’s cooperation on ICH E5
- Suggested permanent representative of APEC on ICH GCG

- **Development--Harmonized Guidelines or ‘Commonality in Regulatory Guidelines’**
- Clinical Trials – infrastructure; regulation; patient safety
- Training, capacity building and education
- IPR – data exclusivity; IP issues in the regulatory framework
- Other topics: Examine ICH and the aim/value of partnership
Examine policies – regulatory systems
- Examine and agree core principles of regulation
- **Tripartite Self Assessment**
- Core competencies
- ‘Needs assessment’ – training, education, infrastructure etc

- **Principles of Operation**
- Activities should be under the umbrella of APEC
- ‘APEC-wide’
- Terms of Reference will be prepared
- Participation should be open to regulators (government), industry and academia
- Any activities/agreements will be flexible and should take account of societal or cultural needs
- Participation in topic discussion should be voluntary
- Participation and activities will be contingent on resources
- Any economy can raise new related topics
- Meetings should leverage other international fora to most efficiently use resources

3. Manufacturing and marketing

Broad and lively discussion in three main areas

- a. Role of regulation in assuring quality products
- b. Counterfeit drugs and their impact on society
- c. Trade and investment in life sciences

Guiding Principles

- Transparency of process
 - Public notice
- Dialogue
 - Meaningful input into development of regulation
 - Active collaboration among all groups: regulators, academics, industry
- Due Process
 - Including right of appeal

Role of Regulation

- Quality standards assure safe and effective medical products throughout the APEC region
 - For entire supply chain
- Quality standards to assure integrity of product use
- Not command and control but trust and verification
- Uniform adherence to high level of quality

Role of Regulation: Actions

- Conduct self-assessment to determine current status relative to best practice
 - WHO 1992
 - ICH Q7A
 - ISO 13485
 - National standards
- Identify gaps and build capacity as needed
- Establish an expert working group to recommend a uniform quality standard

Counterfeit Medical Products

- Now not only a health risk but an actual impact on health
- Now not a cost of doing business but a cause of destruction of business
- Long-range goal is to shift from combating counterfeiters to preventing counterfeiting

Counterfeit Medical Products: Actions

- Conduct self assessment to determine extent of counterfeiting and to understand scope of impact
- Build on WHO network of contact points among APEC economies to share information and to deal with crises

- Create public-private sector partnerships within and among APEC economies to combat counterfeiting
 - Identify most significant resources of counterfeiters
 - Share best practices, including dealing with internet fraud
- Establish uniform enforcement, penalty, and risk of being caught

Trade and Investment

- Sound investment built on legitimate claims of quality, safety, and efficacy
 - From herbal medicinals to products of recombinant technology
- Branded products produced with the certainty of quality under agreed upon standards

Trade and Investment: Actions

- Conduct self-assessment to identify one or more areas within each APEC economy where contributions to life sciences innovation may be established most quickly and effectively
 - Consistent, transparent market regulations
 - Regulatory framework based on sound science and international practice

4. Health Services

The Health Services breakout session agreed on the importance of ensuring the recognition and value of life sciences innovation in health care delivery systems, with the ultimate aim of improving health and quality of life of patients in APEC. There was a general agreement that in order to achieve this end, APEC policy makers initiate a process that helps APEC members achieve the following objectives:

- Develop more inclusive, open and transparent processes for setting health care policies, which solicit and take into account the concerns of the range of stakeholders, including the life sciences industry, patients, and health care providers;
- Develop a more integrated internal approach to policy making on health care delivery issues, in which relevant government agencies such as health, finance, trade and investment and other agencies work together to develop more coordinated approaches;
- Develop better means of monitoring performance and quality of health care delivery systems, including for example, accreditation systems.

As a first step, the group recommends that APEC members meet in the coming year to develop a menu of best practices in these areas, as well as discussing other possible concrete means of cooperation.

APPENDIX III: Report of the 2nd Life Sciences Innovation Forum:
September 16-17, Penang, Malaysia

Representatives of 13 APEC economies (Australia, Canada, China, Hong Kong China, Indonesia, South Korea, Malaysia, Mexico, New Zealand, Singapore, Chinese Taipei, Thailand, United States) participated in the second APEC Life Sciences Innovation Forum (LSIF II) held on September in Penang, Malaysia under the Chairmanship of H.E. Suwit Khunkitti. The forum was hosted jointly by the State Government of Penang and the Malaysian Ministry of Science, Technology and Innovation (MOSTI). Life Sciences experts from Europe contributed to discussion.

The main objective of LSIF II was to review the draft strategic plan, discuss best practices that could be included in the plan, and identify collective actions going forward. There was agreement that the strategic plan was on the right track, that it accurately reflected the work of LSIF I and Expert Working Groups, and that the plan would benefit from expanding on some of the concepts. LSIF II plenary and discussion forums thus expanded and added more clarity to the recommendations. Best practices covered creating incentives for innovation; a holistic approach to life sciences innovation; and technology and infrastructure for Life Sciences. Opportunities for collective action in life sciences were identified as including financing innovation; harmonization initiatives; cooperation for human capital development; and prospects for cooperative projects to develop the necessary innovations to address the early detection and prevention of diseases in the region.

Presentations on these topics were made by distinguished experts, including Malaysia's Minister of Science, Technology and Innovation, H.E. Dato Dr. Jamaluddin Jarjis; the Chief Minister of Penang, H.E. Tan Sri Dr. Koh, Tsu Koon; H.E. Minister Suwit Khunkitti, Chair LSIF; and, Nobel Laureate Dr. Lee Hartwell, President and Director of the Fred Hutchinson Cancer Research Center (FHCRC). Among other things Dr. Hartwell invited LSIF member economies to participate in cooperative research projects on the early detection of chronic diseases, as a contribution to outcomes on Leaders instructions in this area. Four APEC economies (South Korea, Malaysia, Singapore and Thailand) are currently considering participating in these projects with the FHCRC. A series of independently supported Pacific Health Summits will be launched in June 2005 focusing on early detection and prevention and policies that would support associated emerging technologies. It was recommended that APEC welcome the launching of the Pacific Health Summits and that consideration be given to LSIF representation at these Summits. Mexico drew attention to the Global Health Summit that Mexico is hosting in November, 2004 in conjunction with the WHO.

LSIF II discussed and proposed recommendations in all these areas for inclusion in the strategic plan. These recommendations were subsequently developed in breakout discussion forums and included in the draft strategic plan (attached). Interestingly, revisions to the strategic plan included points in common from the four discussion forum groups (research, development, manufacturing and marketing, and health services) in 9 specific areas. These were:

1. The strategic plan should provide guidelines for economies to support life sciences innovation and thus the tone of recommendations to Leaders should reflect that objective.

2. Greater specificity in the scope, coverage and definition of life sciences innovation products and services reflected in the plan extending to information technology/biometrics; scientific and medical devices; diagnostics; medicines; health care services; and, treatments.
3. A redefinition of a cooperative approach to the harmonization of standards to better reflect the intent to move towards a global system of international best practices and guidelines.
4. The need to recognize and build on activities already on-going in the region.
5. Greater definition of the need for LSIF activities to link with other relevant APEC working groups and taskforces such as the ISTWG and Health Taskforce, and the work of other international bodies.
6. The need for a competitive approach to fiscal incentives for R&D consistent with the WTO.
7. A common understanding on the goals of cooperative initiatives such as the Pacific Health Summit and their relevance to LSIF activities.
8. Strengthen education recommendations and proposed activities to include continuing education programs for all life sciences professionals.
9. The desirability of continuity in the composition of expert groups.

Representatives from Chinese Taipei and Thailand presented the outcomes of the APEC LSRA pilot projects conducted in August and September with the assistance of expert facilitators Dr. Edward Bramley-Harker (NERA), Dr. Stephen Cook (GSK), and Professor Dr. Ellick Wong (University of Singapore). It was felt that (1) the readiness assessments needed to be revised to better reflect the goals, operating principles and best practices of the strategic plan; (2) more specific guidance needed to be given to economies on how to approach the assessments; (3) there was a continuing need for expert facilitators to assist economies in the assessment process; and, (4) examples of best practices needed to be provided. LSIF II agreed to a proposal from the Chair of LSIF II that technical experts from interested APEC economies convene in Bangkok in the 2nd quarter of 2005 to ensure that economies understood what was needed to successfully complete a life sciences readiness assessment and review examples. Chinese Taipei and Thailand undertook to provide LSIF with comprehensive reports on their experience with LSRA and suggestions for improvement.

LSIF II discussed the need for specific guidance to Leaders on ways to implement the strategic plan and the need to secure “buy in” from a broad range of public and private sector agencies and entities. To that end the LSIF Chair proposed that he convene in Bangkok an informal meeting of APEC Ministers Responsible for Life Sciences in parallel with the technical experts group in the 2nd quarter of 2005 with the intention of communicating the results of that meeting through the LSIF to Trade and Finance Ministers, among others. LSIF II revised the implementation schedule in the strategic plan accordingly.

Finally, in order to meet the deadline of November 2004 set by Ministers and Leaders for the presentation of the strategic plan, LSIF II requested senior officials at SOM III to endorse the draft strategic plan in principle and instruct LSIF to finalize the plan by October 18, 2004 for intercessional review by the SOM preparatory to transmittal to Ministers and Leaders at their November 2004 meetings.

APPENDIX IV Reports of the Life Sciences Innovation Planning Group

Report to the LSIF Planning Group 9/27/04

REPORT OF THE LIFE SCIENCES INNOVATION FORUM PLANNING GROUP

1. The Life Sciences Innovation Forum (LSIF) Planning Group met on September 27, 2004 in Santiago, Chile, chaired by Barbara Norton of the United States, and assisted by Dr. Sumol Pavittranon of Thailand as the National Focal Point and LSIF secretariat representative. Attending the meeting were officials from 11 economies: Australia, Canada, Chile, China, Indonesia, Korea, Malaysia, Mexico, Chinese Taipei, Thailand and the United States. Australia indicated that it would provide comments on the LSIF draft Strategic Plan after a new government was in place.

REPORT OF THE 2ND LIFE SCIENCES INNOVATION FORUM

2. The Planning Group Chair reviewed the background to the development of the strategic plan, noting that the basic elements and framework for the plan emerged from LSIF I in August 2003 and were endorsed by Ministers at their October 2003 meeting in Bangkok. At that time Ministers and Leaders also requested that the strategic plan be finalized for review by Ministers and Leaders at their November 2004 meetings in Santiago. In response to Ministers instructions, Expert Groups worked throughout this year to add the required detail to the basic principles and framework. The work of the Expert Groups was reviewed by the LSIF Planning Group meeting at SOM I, and by the LSIF Chair, Vice Chairs and Discussion Forum Chairs and was incorporated into the strategic plan which was submitted to the September 16-17 LSIF II in Penang for review. Comments made at LSIF II were assimilated by the Discussion Forum Chairs and incorporated by the small drafting group into strategic plan (2004/SOMIII/LSIF/0003) which was circulated in draft form to the Planning Group in advance of the September 27 meeting.

3. Dr. Sumol Pavittranon reported on the outcome of LSIF II (attached), noting that presentations were made at the forum by a number of distinguished Ministers and the 2001 Nobel Laureate in Medicine, Dr. Lee Hartwell. She observed that LSIF II considered that the plan was on track with Ministers and Leaders instructions and enumerated the nine general comments in common that emerged from the Discussion Forums, noting that these were reflected in the latest version of the strategic plan, including, importantly, ensuring that the scope of the plan covered medical devices and diagnostics as well as pharmaceuticals and treatments.

4. Because of the need to provide specific guidance on the LSIF Readiness Assessment (LSRA) template as a means of implementing the strategic plan, the LSIF II seeks APEC endorsement of LSIF Chair's intention to host a technical working group in the 2nd quarter of 2005 to ensure that economies understand what is needed to successfully complete a LSRA and review examples. Because of the need to secure good communication with a broad range of public and private sector agencies and entities to ensure successful implementation of the strategic plan, and provide guidance to Leaders on implementation, LSIF II also seeks APEC endorsement of LSIF Chair's intention to hold an informal Meeting of Ministers Responsible for Life Sciences in the 2nd quarter of 2005 in Bangkok. The Planning Group agreed with this approach.

REVIEW OF THE STRATEGIC PLAN

5. Comments on the strategic plan were made in the Planning Group by Mexico, Thailand, Malaysia and Chile. Mexico requested clarification of the goals of the Pacific Health Summit and how the plan would be implemented. The Chair assisted by an expert explained that LSIF II agreed to welcome independent initiatives such as the June 2005 Pacific Health Summit and Mexico's November 16-20, 2004 Global Health Forum and would examine the outcomes of those forums as part of LSIF intention to draw on and not duplicate the work of other international meetings that was relevant to the LSIF mandate. It was also noted that implementation of the strategic plan would largely be conducted through addressing capacity building needs that emerged from the LSRAs. Mexico suggested that the plan emphasize the importance of creating a good business environment for life sciences innovation.

6. Chile indicated that President Lagos would endorse the plan subject to a few changes including ensuring the plan was TRIPs consistent and a few revisions in wording such as in the health services section. Chile will submit those comments in writing. Dr. Sumol clarified certain points of substance on health services.

7. The Planning Group Chair requested that comments from economies be submitted no later than October 18 so that these could be incorporated for intersessional review by the SOM and endorsement for transmittal to Ministers and Leaders in November. In so doing, she noted that the strategic plan had already been substantively reviewed by economies, Chair LSIF, Vice Chairs, the Chair of the Expert Groups, and Discussion Forum Chairs.

8. Thailand noted that it planned to table a paper on fighting AIDs for APEC's possible future consideration.

LSIF READINESS ASSESSMENTS

9. Chinese Taipei and Thailand presented their reports on the LSRA pilot projects they had conducted with the help of expert facilitators in August-September 2004. It was noted that LSRAs needed to be revised to make them more user-friendly and consistent with the LSIF strategic plan. Thailand outlined its progress and intentions on the readiness assessment for developing the four areas of the Life Sciences Innovation value chain: research, development, manufacturing and marketing, and health services. The Planning Group Chair noted that the LSRAs were an important step in the implementation of the plan and that some economies may require the assistance of facilitators to complete the LSRA template.

ICH SELECTION CRITERIA

10. LSIF PG Chair reported on discussions with representatives of the International Conference on Harmonization's Global Cooperation Group (ICH GCG) in Penang, concerning LSIF representation at ICH, which will require a significant revision of the draft ICH selection criteria to reflect ICH GCG desire for continuity in representation at the same time as ensuring that there was adequate rotation among APEC economies, and addressing resource allocation. ICH is offering two seats for LSIF at the ICH GCG meetings. However, ICH will only meet the cost of one participant. The Planning Group agreed that LSIF Vice Chair Dr. Pakdee would

attend the November 4 ICH GCG meeting in Yokohama, funded by the ICH and accompanied by a second representative, who would attend the spring 2005 ICH GCG meeting. The Chair noted that formal nominations and resumes had been received from two of the five economies that had indicated interest in participating in the ICH GCG and requested that nominations be forwarded to her by October 15. The APEC Secretariat would then draw up a slate of candidates, which would then be circulated to the Planning Group. In the meantime, the selection criteria would be revised for intersessional review by the Planning Group. Australia indicated its intention to clarify the status of its intended nominee.

OTHER BUSINESS

11. The Planning Group welcomed the support of the medical life sciences industry for the strategic plan and the industry's invitation for APEC officials and Ministers to participate in a reception on November 18, 2004 hosted by Johnson and Johnson at the Marriott Hotel to celebrate the presentation of the LSIF strategic plan to Ministers and Leaders. The APEC Secretariat will include this event on the APEC calendar.

Report of the Life Sciences Planning Group 2/28/04

1. The Life Sciences Planning Group met on February 28, 2004 in Santiago, Chile. Fourteen economies were represented at the meeting: Australia; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; Korea; Mexico; New Zealand; Philippines; Chinese Taipei; Thailand; and United States.
2. The Planning Group Chair (United States) recalled the instructions of Ministers and Leaders instructing the Life Sciences Innovation Forum to draft a strategic plan for life sciences for review and endorsement by Ministers and Leaders in November 2004. The Chair noted that drafting the strategic plan was an ambitious undertaking, and thanked Thailand for its excellent leadership which was keeping the initiative on schedule toward the ultimate goal of developing the strategic plan by November 2004.
3. The Chair next reported on outcomes of the Life Sciences Experts Meeting, which the chair of the Life Sciences Innovation Forum, Thai Deputy Prime Minister H.E. Suwit Khunkitti, had convened in Khon Kaen on 12-13 February 2004. She noted that participants at the Experts meeting had agreed that a further Experts meeting would be needed, and that this would be held in Washington DC in June on the margins of other international life sciences meetings, including the International Conference on Harmonization.
4. The Chair then reported on the status of the capacity-building initiative which had been circulated and approved by Planning Group members in January. The proposal for facilitators to assist volunteer economies in conducting readiness assessments will be sent to CTI and SOM for endorsement, and then to the Budget Management Committee for consideration at their meeting at the end of March. The Chair noted that several economies had already expressed interest informally in volunteering to take part in the readiness assessment project, and invited economies to formally indicate their interest.
5. The United States reported that the International Conference on Harmonization, Global Cooperation Group (ICH GCG), had sent a letter on December 18, 2003 to the LSIF Chair inviting APEC to nominate one member to serve as a permanent representative to its meetings. The LSIF Chair had acknowledged the letter indicating that it would be discussed at the LSIF Planning Group in Santiago. There was discussion of the prospect of an interim representative pending the development of a selection process.
6. Thailand confirmed the interest of the Government Vice Chair of the LSIF, Dr. Pakdee Pothisiri in serving as the interim representative to the ICH GCG meeting in June, and also indicated that Dr. Pakdee would like to be considered as the permanent representative. Australia, China, Korea, and Chinese Taipei each reported that they also had candidates interested in serving as APEC's permanent representative to the ICH GCG.
7. The Planning Group agreed on a three-point plan of action: (1) The Planning Group supports APEC being permanently represented on the ICH GCG and requests SOM endorsement; (2) the three LSIF Vice-Chairs should expeditiously (and intersessionally)

draw up a list of criteria by which to judge the suitability of the various candidates, and to consider the terms and possible rotation schedule for APEC permanent representatives to the ICH GCG; and (3) In the meantime, Dr. Pakdee would serve as the coordinator and the interim representative for the purpose of the June 7, 2004 ICH-GCG meeting in Washington DC and the ICH GCG should be so informed as soon as possible.

8. The Planning Group Chair noted that the next meeting of the Life Sciences Planning Group would take place during the SOM II period. She further noted that the second Life Sciences Innovation Forum would take place in mid-September, and that Malaysia had informally expressed interest in hosting this event.

Attachment

LSIF: Report to LSIF Planning Group

At their October 17-18, 2003 meeting in Bangkok, Thailand, APEC Ministers instructed the Life Sciences Innovation Forum (LSIF) to convene expert groups intersessionally to develop the strategic plan for life sciences innovation in the region for review and endorsement by APEC Ministers and Leaders at their November 2004 meetings. Accordingly, the Chair of the LSIF, H.E. Suwit Khunkitti convened a small expert group meeting February 12-13, 2004 in Khon Kaen, Thailand under the chairmanship of Dr. Pakdee Pothisiri, Government Vice-Chair of the LSIF, supported by industry Vice-Chair Richard Smith and Academic Vice Chair Dr. Peter Sheehan. Participants were identified by LSIF Vice Chairs in consultation with LSIF I Discussion Forum chairs and the LSIF Planning Group. A participants list is attached.

The four expert groups (research, development, manufacturing and marketing and health services) made an excellent start in identifying the specific goals and operating principles applicable and of priority to their particular area of expertise based on the outcomes of LSIF I (see attached). A draft working matrix of LSIF I outcomes developed by the LSIF Planning Group Chair in consultation with LSIF Chair and Vice Chairs was used as a guide (see attached draft matrix). It was felt that a further meeting of expert groups was needed to review, further refine and elaborate on the preliminary outcomes from Khon Kaen. The current proposal is to hold this meeting in June in Washington DC as many senior regulators, academics and industry representatives will convene in Washington at that time for other international life sciences related meetings. In the meantime, expert group chairs will work intersessionally in consultation with the LSIF Chair, Vice Chairs and the LSIF Planning Group chair to further develop a draft framework for the strategic plan for review at the June meeting. A progress report will be presented to CTI/SOM II.

LSIF Planning Group members are asked to identify an appropriate expert who will be participating in the June series of meetings in Washington DC. LSIF Chairs and Vice Chairs believe that we should not restrict expert participation to APEC economies as there are a number of world experts in the life sciences area upon whom the forum should draw. For example, the Khon Kaen expert group meeting included Dr. Edward Bramley-Harker, a world renowned health services expert who chaired that group in Khon Kaen and made a significant contribution to advancing the APEC LSIF agenda.

The Expert Group meeting in Khon Kaen also had preliminary discussions on the December 18, 2003 invitation to the LSIF from the International Conference on Harmonization (ICH) to nominate a permanent representative to its Global Cooperation Group (GCG). It was felt that this was an historic first for APEC. The LSIF Chair has responded in the affirmative on an interim basis, indicating that the government Vice Chair would coordinate APEC's response pending discussion at SOM I and related meetings in Santiago. A number of APEC economies have indicated interest in serving as the LSIF representative to the GCG.

Finally, the Expert Groups discussed ways of preparing life sciences innovation readiness assessments and the proposal to the APEC Budget and Management Committee for capacity building assessments.

2004 Next Steps

- Expert groups work intersessionally to further develop the strategic plan framework and readiness assessments.
- BMC approval of capacity building pilot project
- Progress report to SOM II.
- Expert groups convene in Washington, DC in June
- Draft strategic plan circulated intersessionally in July/August
- Draft strategic plan and results of pilot readiness assessments presented to LSIF II in mid-September
- Draft strategic plan approved by SOM III for transmission to Ministers and Leaders
- Strategic plan presented to Ministers and Leaders for endorsement at their November meetings in Santiago.

Report of the Life Sciences Innovation Forum (LSIF) Planning Group 5/26/04

The LSIF Planning Group met on May 26, 2004. Representatives attended from Australia, Canada, Chile, China, Hong Kong China, Indonesia, Malaysia, Papua New Guinea, the Philippines, Chinese Taipei, Thailand and the United States.

The Planning Group Chair briefed on developments since the February 28 Planning Group Meeting and provided a summary overview of the agenda. The U.S. reported on preparations for the June 11-12, 2004 Expert Working Group Meeting in Washington D.C. and noted that an updated agenda will be circulated shortly. Approximately 50 experts from Australia, Canada, China, Chinese Taipei, Hong Kong, Malaysia, Singapore, Thailand and the U.S. have already registered. The Chair noted that additional experts from economies would be welcome.

The Planning Group Chair reviewed the draft LSIF Readiness Assessment template that will be discussed by the June EWG meeting for further definition of the operating principles and targets. The template will be circulated again for review prior to the July-August commencement of pilot project assessments. The drafting committee representative clarified that the template is a working document that could be further refined as a result of the project assessments. Chile requested that all acronyms on the template be identified. Thailand confirmed its interest in conducting a pilot readiness assessment. China, Chinese Taipei, and the Philippines all indicated provisional interest.

The Planning Group Chair reviewed progress on developing the LSIF Strategic Plan noting that it will be based on the consolidated outcomes from LSIF I and Khon Kaen EWG. The June EWG meeting will further define the best practices that support the operating principles. The June EWG will provide an overview tied to the goals of the LSIF, and an executive summary and explanatory notes. The Chair noted that the Vice Chairs reviewed the consolidated outcomes and that comments from the Government Vice Chair were subsequently incorporated. This set of documents will constitute the Strategic Plan, which is due by the 2004 Ministers and Leaders Meeting. The draft plan will be circulated to the Planning Group for review in the third week of June with comments due by July 31. The drafting committee will incorporate comments and forward the revised plan to the Chair and Vice-Chairs for review and presentation to LSIF II with final review at SOM III.

The Planning Group discussed the ICH selection criteria and process for LSIF's participation at the ICH Global Cooperation Group's meetings. The group agreed to a minor modification to the selection criteria and agreed to revise the selection process as follows: the Planning Group would draw up an annual slate of candidates based on nominations from APEC economies. Nominations must include CVs and a letter of justification. The APEC Secretariat will serve as a clearinghouse for this process and will forward the nominees to the LSIF Chair and Vice-Chairs for final selection. The group agreed that an alternate would be appointed from the slate of candidates. The LSIF representative would serve for a term of one year. A revised document reflecting the changes to the selection criteria and process will be circulated to the Planning Group for further review.

The U.S. reported progress on a possible fiscal year 2005 U.S.-funded capacity building project on Good Clinical Practice.

Malaysia confirmed its offer to host LSIF II in Penang on September 15-16, 2004. More information will be circulated intersessionally including a call for suggestions for participants and speakers.

Report to the APEC SOM on the Life Sciences Innovation Forum
by Professor Dr. Pakdee Pothisiri
Deputy Permanent Secretary, Ministry of Public Health of Thailand
Vice-Chair of the Life Sciences Innovation Forum
22 August 2003, Phuket

Thank you Mr. Chairman,

On behalf of the APEC Life Sciences Innovation Forum Chairman, Mr. Suwit Khunkitti, Deputy Prime Minister of Thailand, I would like to present a brief report on key outcomes of the Forum, which held its inaugural meeting in Phuket during 14-15 August this year.

The Forum was convened with a view to implementing the APEC Leaders' instructions on the development of a strategic plan for life sciences innovation in the region. It was attended by over 200 high level participants from 17 economies drawn from academia, government and industry. The Forum attracted experts and noted policy makers such as Her Excellency Ms Sudarat Keyuraphan, the Thai MOPH Minister, HE Mr. Manual Dayrit, the Secretary of Health of the Philippines, Juan Enriquez, Harvard Business School, the author of the book "As the Future Catches You"

The Forum was held as plenary as well as panel discussion and break-out sessions to address and identify areas of cooperation in the four main segments of the life sciences innovation value chain, namely, research, development, manufacturing and marketing, and health care services. Several key themes emerged that were considered vital elements of a framework for the strategic plan. The written report of the key outcomes of the Life Sciences Innovation Forum has already been submitted to SOM.

The Forum recognized life sciences innovation as a critical area for growth and socio-economic development. The promotion of life sciences requires political leadership and commitment from the top, and depends on the proper policy environment, public-private partnership, sound basic education, human capacity, and efficient and effective delivery of patient-focused products and services. Transparency, meaningful dialogue with stakeholders and recognition of due process are among guiding principles to move forward the development of life sciences. Capacity-building will also be critical.

A number of immediate outcomes were identified as recommendations for Leaders' endorsement in October 2003, including, among others, agreement in principle to harmonize quality standards for life sciences products and services according to international best practices; and an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

As for the time-frame for the development of the strategic plan, given that life sciences technology is fast moving, the Forum recommends that the strategic plan be finalized by the time of the APEC Leaders Summit in 2004. It also recommends that expert groups work intersessionally to develop a road map encompassing best practices for each of the four main

segments of the life sciences innovation value chain for endorsement by Leaders at their 2004 Summit.

In all, the Forum was an excellent start for enhancing APEC's cooperation in the life sciences sector. I therefore hope that SOM will endorse the recommendations of the Forum.

Mr. Chairman,

I wish to add that Thailand takes the issue of life sciences innovation seriously. As a concrete step to promote life sciences innovation, we are establishing Thailand Center of Excellence for Life Sciences, which, as announced by Deputy Prime Minister Suwit during the Forum's meeting, will become operational in January 2004. This Center will complement our efforts to enhance cooperation in this area within APEC as well.

Finally, I would like to take this opportunity to thank the United States for this timely initiative and for their cooperation in making the first meeting of the Forum a real success.

Thank you.

Summary Report of Life Sciences Innovation Forum (LSIF) Planning Meeting to CTI May 2003

Purpose: For Consideration
Submitted: US

The ad hoc LSIF Planning Committee was convened by the Chair, Barbara Norton, May 21, 2003 in Khon Kaen. A participant list is attached (from Catherine Wong, APEC Secretariat).

The first Life Sciences Innovation Forum will be held August 14-15, 2003, in Phuket Thailand as part of SOM III and related meetings. The Forum is expected to attract up to 300 participants and speakers. The Planning Group engaged in extensive discussion of the Forum Program, Speakers, Chair and Vice-Chairs. An updated program has been drafted, which reflects input and suggestion from the Planning Group (see attached for your review). Several economies indicated great interest in the LSIF from all three involved sectors--academia, private sector and government. Additional speakers names and nominations for Chair and Vice-chairs are continuing to be submitted up to the deadline of May 30. The Planning Group agreed that invitations to speakers would be issued in the first week of June. Each economy will be responsible for registering participants from their economy. A number of nominations have been received for Chair and Vice-chairs. The Planning Group will continue to work intersessionally to finalize the speakers, the placement of the speakers on the agenda, and Chair and Vice-chairs

Action requested: Endorse Life Sciences Innovation Forum Program as a working agenda to organize the Forum.

Report to CTI on Life Sciences Innovation Planning Forum February 2003

1. The meeting was called to order by the Chair. Economies attending included Australia; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; Korea; Malaysia; Mexico; New Zealand; Singapore; Chinese Taipei; Thailand; and the United States. The APEC Secretariat also attended the meeting.
2. An expert in the field made a presentation on the Life Sciences Value Chain.
3. The Chair opened the floor to discussion of the Terms of Reference (TOR), noting that these would need to be finalized at the February meetings, so that the Forum can be held in conjunction with SOM III and substantive work can begin intersessionally on the agenda and scope of the Forum. Extensive comment and discussion ensued, resulting in suggested amendments to the TOR and suggestions of topics for the Forum to cover. It was agreed that a further Planning Group meeting would be held in conjunction with SOM II.
4. The Chair adjourned the meeting, informing participants that a new draft, incorporating comments raised in the discussion would be distributed to all economies' boxes, asking for further comments on the new draft by end of day Feb 14.

APPENDIX V: Goals, operating principles and best practices:
Report of the Expert Working Groups

Consolidated Outcomes from June 2004 meeting in Washington DC

RESEARCH GROUP

Goals

- To promote high-quality research⁷ in all areas of the life sciences value chain⁸.
- To promote the application⁹ of the outcomes of research.

Operating Principles¹⁰

- Policies, priorities and strategies
 - Member economies will, individually and together, develop research policies, priorities and strategies that are:
 - based on identified health priorities¹¹ and economic objectives
 - based on detailed policy research and evidence
 - subject to periodic reviews.
- Human capital and education
 - Member economies will give priority to sufficient number of skilled researchers in life sciences.
 - The development of human capital will be pursued
 - at all education levels
 - through collaboration among economies
 - through public and private collaborations.
- Collaboration and networking
 - Collaboration and networking will be based on trust, shared benefits and openness.
 - Member economies will work together to:
 - Support research that leads to improved health outcomes
 - Encourage and facilitate collaboration and networks at all levels and between public and private sectors.
- Infrastructure and coordination

⁷ All forms of research including basic, applied, and development research, in both public and private sectors

⁸ This covers research in all four aspects of the life sciences value chain

⁹ Broadly defined as encouraging the many different forms of applications, e.g., more research, translation, commercialization, communication of research to the public, and using of the results in formulating government policy

¹⁰ In most, if not all, of these areas, capacity building will be of prime importance

¹¹ Having regard to the existing burden of disease and emerging disease

- Member economies will, individually and together, work to:
 - Develop strong and viable organizations and other infrastructure to support research
 - Establish centers of excellence with critical mass around research priorities
 - Provide adequate infrastructure to support research priorities
 - Encourage coordination between national research agencies
 - Develop mechanisms to align research activities on health priorities.
- Ethics and regulation
 - Member economies will, individually and together, work to ensure:
 - Appropriate and transparent ethical frameworks for research on health
 - Appropriate and transparent regulatory frameworks for research on health
 - Appropriate systems and mechanisms to support good research practices according to international best practices
 - Adequate training of personnel in the regulatory and ethical frameworks
 - Protection of intellectual property.
- Financing of research
 - Member economies will, individually and together, work to:
 - Ensure adequate financing of research on health priorities
 - Encourage public-private partnerships in financing research on health priorities
 - Improve access to private funding for the application of research outcomes.
- Best practices
 - Member economies will, individually and together, work to:
 - Utilize best practice peer review in the assessment of research
 - Ensure research is conducted by qualified personnel
 - Ensure clinical trials comply with relevant international standards
 - Ensure regulation of research is undertaken by qualified personnel
 - Regularly assess research practices and outcomes
 - Ensure consistent quality standards of research facilities.
- Public awareness, confidence and support
 - Member economies will, individually and together, work to
 - Communicate widely research policies, priorities, strategies and outcomes
 - Involve the community in research activities
 - Inform and consult the community on specific research issues.

DEVELOPMENT GROUP

Overall Goals

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- ,PSURYHGFOQIFDNDQJQUWVFWUH
- (IIFWYH) HFKDQJVP WDMQDKQFHMFHFWWRIQQR YDMRQV

Operating Principles

- Human Capital
 - Member economies will ZRUNRHXQRXDJ HQYHW HQFRQDERUDWYHUMHDFK JUDQURJ UDP VEHZ HQ\$ 3 (& HFRQRP IHV .
 - Member economies will establish collaborative public-private research grant programs to support the development of human capital in LSIF.
 - Member economies will work to develop JR YLQP HQWS XEJF VFWWRUH FRPSHWQFLM, including:
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 - 0 HPEHFRQRP IHZ IQZRUNWRIP SURYKXP DQFSDMWRFNWURXJ K
 - Integration of life sciences as part of the school curriculum
 - Investment in domestic PhD and postdoctoral grant programs
 - 3 XEJF (GXFDMRQ \$ Z DUHQW\$ URJUDP V
- Organizational Infrastructure and coordination
 - Member economies will establish a IHIDUDP HZ RUNIQFRLSRUDMQJ IQMDJ HQF\ UMHZ RI QHZ SRQFHMJ XGDQHDQGUHJ XDMRQV
 - Member economies will work to establish Centers of Excellence around research priorities
- Physical Infrastructure
 - Member economies will work to e WDEOK 7 WVFVUHMNDQFQGHV
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 - 0 HPEHFRQRP IHZ IQZRUNWRIQYHQDGH XDMUMHDFKIDFQMMWURXJ K SXEQSULDMSDUMHUKISV
- Environment for Investment in Research
 - Member economies will acknowledge the importance of a GHIXDMKXP DQ RU DQJLDMRQDDQGS K VEDQMRXUHFV IQFQGLQJ
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 - 0 HKDQJVP VRFRP P HFILSDUMHUKISVRWDMRQURP EDMF W DSSOHCUMHDFKQDQFRP P HFIDQJDMRQ
 - DHHVRFDS WQDUNHW
- Protection of Intellectual Property

- Member economies will work to ensure adequate training of regulatory and clinical personnel; including:
 - The establishment of Internal Review Boards (IRBs)
 - Member economies will work to release clear guidance to regulated community on clinical trial approval process
- Good Manufacturing Practices
 - Member economies will work to ensure:
 - the adequate training of government personnel, including inspectors
 - Assessment of current domestic practices in relation to international practice (e.g., WHO guidance)
 - Establishment of regulatory framework that recognizes manufacturers with history of adhering to GMPs
 - Performance assessment criteria based on international best practices—adequate infrastructures , indicators and criteria for inspection at the level of the ICH/PICS
- Environment for Capital Investment
 - Member economies will work to ensure:
 - Adequate IP protection defined as consistent with TRIPS
 - Science-based, transparent, predictable, regulatory environment
 - Adequate resources (human, organizational and physical)
 - Transparent market mechanisms including regulations
 - Mechanisms for public-private partnerships
- Services Environment
 - Member economies will work to establish a services environment that is:
 - Inclusive, open and transparent process
 - Interagency involvement and coordination
 - Accreditation systems
 - Ethical committee
 - GLP/ISO 17025 Laboratory
 - OECD GLP Laboratory

MANUFACTURING AND MARKETING GROUP

Goals:

- To ensure a transparent and science-based regulatory framework for the manufacturing and marketing of innovative life sciences products that will assure the safety, quality and efficacy of the products.
- To ensure the ability of patients to have timely access to innovative products.

Operating Principles

- **Human Capital**
 - Member economies will invest in collaborative research grant programs between APEC economies that:
 - may be used to support investigations into both technology and policy; and
 - are based on the model established by the World Health Organization
 - Member economies will establish collaborative public-private research grant programs to support the development of human capital in LSIF.
 - Member economies will work to encourage human resource development in the private sector; that is, continuing education for employees, that:
 - provides an opportunity for partnerships involving professional societies that are already established in the APEC economies
 - may lead to the establishment of an APEC-wide federation of those professional societies that support the life sciences industry in a region
- **Physical Infrastructure**
 - Member economies will work to develop adequate information technology infrastructure that ensures the ability for regulators to communicate across economies
- **Environment for Investment in Research**
 - Member economies will establish a transparent, predictable, and science-based regulatory framework for transition from basic research to applied science as one of the most important operating principles
 - access to capital markets likewise is a necessity for an APEC economy to implement successful manufacturing and marketing capacity
- **Protection of Intellectual Property**
 - Member economies will implement a legal framework for patent protection, adequate infrastructure, and resources for enforcement of laws and regulations in order to protect intellectual property.
 - Acceptance of intellectual property rights must be consistent with WTO membership commitments.
- **Legal Framework with Due Process**
 - Member economies will work to establish rule of law that includes:
 - An adequate mechanism for right of appeal
 - Access to regulatory findings, especially in case of negative findings
 - An open and transparent process without risk of abuse to the regulatory authority

- A forthcoming regulatory authority with adequate information to support its findings without being subject to repeated rounds of questioning on the same topic
- Transparency in Development of Regulations
 - Member economies will work to establish a legal framework that incorporates adequate notice and comment into regulatory development
- Regulatory Framework: Sound Science
 - Member economies will work to implement a science-based regulatory framework where decisions are made firmly on the basis of safety, efficacy and quality and that:
 - Emulates appropriate international standards and international best practices such as ICH, WHO, ISO
 - Includes a clear and published process for drug development and regulatory approval, a mechanism for industry to consult with regulatory authorities, and a mechanism for appeal
 - Contains predictability and published timeframes for regulatory processes, with an aim to have a similar timeframe timelines for all Member economies
 - Takes into account ICH guidelines Q8, Pharmaceutical Development and Q9, Risk Management currently under development
 - When appropriate, public scientific advisory panels should be used for specific scientific issues related to a marketing application, new technology, or new regulatory initiative
- Good Manufacturing Practices (GMP)
 - Member economies will, individually and together, work to provide adequate training of government personnel, with the same training to be delivered to inspectors and industry personnel
 - Training design should take into account both current domestic practices and international best practices
 - Member economies will establish a regulatory framework that recognizes manufacturers with a history of compliance to GMP, with:
 - Performance based on international best practices
 - PICS (Pharmaceutical Inspection Cooperation Scheme) as mechanism for documentation and mutual recognition across APEC economies
 - Member economies will adopt an international baseline guidance for interpreting GMP.
 - Adherence to baseline good manufacturing practice should be acceptable in most cases
- Environment for Capital Investment
 - Member economies will implement a science-based, transparent, and predictable regulatory environment that provides protection of intellectual property in order to encourage adequate capital investment

HEALTH SERVICES GROUP

Goals

- To create an environment that is conducive to trade and investment in life science innovations
- To foster an inclusive and integrated approach to policymaking and implementation (policymakers need to co-ordinate their activities and consult with stakeholders)
- To monitor the quality and performance of health systems to ensure appropriate use of innovations

Operating Principles

- Human capital and education
 - Member economies will make necessary investments in human capital to ensure that economy is able to collaborate and lead research activities.
 - Investments may include cross-country collaboration and public-private partnerships
 - Within the economy, members will educate their science base to ensure appropriate dissemination of new innovations
- Organizational infrastructure and co-ordination
 - Member economies will measure and assure the quality of research infrastructure
- Physical Infrastructure
 - Member economies will invest in IT systems and infrastructure that are:
 - coordinated, with interoperability and common standards across the health system
 - transparent and efficient tendering
 - equipped with feedback mechanisms to ensure objectives are being met and quality standards enforced
- Protection of intellectual property
 - Member economies will commit themselves to ensuring a legal and regulatory framework is in place to ensure IP standards are ensured and enforced
- Transparent regulatory framework
 - Member economies will work to implement a transparent process for deciding whether an innovation will be available in a health system that includes:
 - fast approval for public reimbursement (e.g. rapid inclusion on a national formulary)
 - efficient price negotiations
 - in the case of a pharmaceutical products, a clear and efficient process for obtaining marketing approval
 - A sensible benchmark is for products to be available privately as soon as they have marketing authorization, with approval for public reimbursement soon after via a clear and consistent process
- Good clinical practices
 - Member economies will work towards health systems with well-trained regulatory and clinical personnel who have clear guidance over processes that include:
 - mechanisms for monitoring quality

- mechanisms for reporting adverse events
- Portability of health insurance
 - Member economies will ensure that, where agreed, patients are able to make choices over where they have treatment
 - Member economies will also encourage the dissemination and take-up of innovations as health care providers start to compete in a broader market for patients
- Informed Patients
 - Member economies will encourage the provision of information about a variety of dimensions of health care, including quality and outcomes of different interventions, health care providers, physicians and patient experience so that patients may:
 - be involved in decisions about choice of treatment
 - be responsible users of innovations they need to know about their treatment (evidence suggests that compliance with treatment regimes is improved where patients are partners in the treatment process and are informed)
- Informed physicians
 - Member economies will work to ensure policymakers are willing and capable of:
 - disseminating good quality information to physicians
 - ensuring the continuing medical education of physicians
- Evidence-based medicine
 - Member economies will work to:
 - encourage evidence-based medicine subject to the condition that it is applied consistently across the health system, to the range of interventions and not just, for example, to new innovations
 - allow for clinical guidance based on good quality effectiveness and cost information
 - discourage mandatory guidance, which can limit clinical freedoms
- Budget setting
 - Member economies will work to:
 - adopt an integrated approach to budget setting
 - avoid setting budgets in a compartmentalized way (e.g. keeping prescribing budgets totally separate from other primary care budgets and secondary care budgets)
 - Compartmentalized budget setting may be harmful for health services innovations in that:
 - A risk exists that physicians in one part of a health system are reluctant to use an efficient innovation because it imposes a cost on their budget but the savings are realized elsewhere or many years in the future
 - an innovation that is efficient from the health system perspective may be under-used because individual physicians do not see their budgets or the benefits from the perspective of the whole system
- Separation of prescribing from dispensing
 - Member economies will work to separate prescribing from dispensing in order to:
 - ensure prescribing decisions are based around clinical needs
 - prevent financial motives from distorting prescribing behavior
- Balanced approaches to cost containment

- Member economies will work to focus on long-term efficiency and sustainability, not on short term cost containment
- Use of traditional remedies
 - Member economies will, where evidence shows sound clinical and efficiency benefits, work to make appropriate use of all types of health intervention, whether modern or traditional

Summary Outcomes of the February 12-13, 2004 Expert Groups Meeting in Khon Kaen.

1. Strategic Plan

It was felt that the strategic plan should be based on clearly identified goals and operating principles supporting these goals. Best international practices should be utilized in developing the strategic plan. The strategic plan should allow individual economies the ability to clearly identify their strengths and weaknesses in segments of the life sciences value chain and provide a basis for developing individual and, where possible, collective APEC action plans, including identification of possible capacity building programs for implementation of the plan, beginning in 2005. Participants agreed that Ministers and Leaders need a document that is both workable and readily understood. As such, the strategic plan would include an executive summary that describes the goals and ways of achieving these goals from a strategic policy perspective.

2. Readiness Assessments

The development and implementation of life sciences innovation readiness assessments was endorsed by Ministers and Leaders in October 2003. It was felt that more work needs to be done on developing specific guidance in each area of the life sciences value chain before the readiness assessments can be fully developed. The expert groups heard a presentation on APEC's E-Commerce readiness assessments and determined that while that may be a valid model, the life sciences innovation sector did not lend itself to the quantifiable standards of the E-Commerce readiness assessments in all areas of the value chain. It was also felt that the life sciences innovation readiness assessments should avoid a questionnaire approach, instead it would be of more value to economies to clearly identify a menu of best practices options that supported the goals. Accordingly, the expert groups recommend that the life sciences innovation readiness assessments be drawn up for review by APEC economies and after the proposed meeting in June. In the meantime, the expert groups recommended that APEC call for 2 or 3 volunteers to participate in a readiness assessment pilot project for presentation to LSIF II in mid-September.

3. Expert Groups

a) Research

The Research Group was chaired by Academic Vice Chair, Dr. Peter Sheehan in the absence of Research Discussion Forum Chair Kim Sze Tan (Malaysia). The group considered in some detail the goals for life sciences research in the proposed strategic plan. This discussion took place in the context of the overall objectives of the APEC Life Sciences Innovation Forum to generate improved health outcomes and stronger economic development in member economies. The group identified two main goals: 1) To promote high quality research in all areas of the life sciences value chain and 2) To promote the application of the outcomes of the research. The proposed goals emphasized the promotion of research broadly defined, including basic, applied and development research in both the public and private sectors, and the application of this research to all elements of the life sciences value chain.

After detailed discussion of the matrix, the group developed draft operating principles to achieve these goals in eight areas, namely:

- policies, priorities and strategies,
- human capital and education,

- collaboration and networking,
- infrastructure and coordination,
- ethics and regulation,
- financing of research,
- best practices, and
- public awareness, confidence and support.

The principles developed in these areas are ones on the basis of which member economies might, both individually for national benefit and together for the benefit of the APEC region as a whole, identify and implement programs of action to achieve the goals. The starting point for such programs should be the identified health priorities of member economies, based on the actual burden of disease, and the contribution of improved capability in life science innovation to addressing those priorities.

b) Development

The Development Group was chaired by Dr. Suwit Wibulpolprasert, Senior Advisor on Health Economics, MOPH Thailand in the absence of Development Discussion Forum Chair John Lim (Singapore). The group held a robust discussion on the appropriate goals and operating principles that supported these goals. It was recommended that the goals as outlined in the matrix be amended to reflect the forward-looking nature of this group. As such, the group proposed three main goals: 1) Effective regulatory infrastructure that enhances innovation; 2) Harmonization of regulatory practices and policies according to international best practices; and, 3) Improved clinical trials infrastructure. The group also recommended a further goal – effective mechanisms that enhance access to innovations – in recognition that this goal might be better placed under health services. The group added an operating principle – public education and awareness programs, reasoning that these were a critical element necessary to achieve all the goals. Operating principles were further modified to reflect consistency with TRIPs with respect to IPR protection.

It was considered that IPR protection underpinned the success of life sciences innovation development in all areas, as did a regulatory framework grounded in sound science with the regulatory process based solely on safety, efficacy and quality. A legal framework with due process, risk and evidence-based procedures, transparent and predictable governmental processes and industry consultation in the regulatory framework were also considered critical factors in the development of life sciences innovation. These critical elements formed the basis for further detailed discussion by the group.

The group considered that an integrated and linked administrative and judicial framework dedicated to IPR protection was essential. The need for clear published process for drug development clearly specifying requirements including advice, consent and consultation available through print and electronic media was highlighted as an example of predictability in the regulatory environment. Other examples discussed by the group included the need for data requirements to be based on international standards (e.g. ICH/WHO); an adequate performance assessment infrastructure including indicators and criteria for inspection based on ICH/PICS; the adoption of ICH GCP and WHO guidelines as a standard for clinical trials; and, accreditation systems based on ethical guidelines and international standards such as OECD/GLP and

GLP/ISO 17025. The group recognized that an adequate and flexible IT infrastructure was an absolute requirement for life sciences product development.

The group concluded that more work needed to be done to flesh out the best practices that would support the operating principles and goals.

c) Manufacturing and Marketing

The group was chaired by Dr. James McArdle, Manufacturing and Marketing Discussion Forum Chair. The group recognized that its relatively small size would necessitate an additional meeting of experts. The group emphasized the need to invest in human capital, including developing the human resource in the private sector through continuing education programs; considered that a transparent, predictable and science-based regulatory framework was one of the most important operating principles that applied to all goals within manufacturing and marketing; and highlighted the need for WTO consistent IPR protection. As with the development group, there was discussion of the need for risk and evidence based procedures; and the adoption of international guidelines and best practices with respect to GMP. Access to capital was considered of importance across all areas of the value chain.

d) Health Services

The group was chaired by Dr. Edward Bramley-Harker in the absence of Dr. Frank Lichtenberg. It looked at the principles and mechanisms within a health system that impact on the incentives to develop and use life science innovations. Within this, the group identified three broad goals: 1) to create a conducive environment for life science innovation, trade and investment; 2) to encourage policymakers to develop inclusive approaches to policymaking and implementation; and 3) to ensure, through monitoring, that the health system is making good use of life science innovations and promoting quality in health care delivery. Many principles within the matrix were considered relevant to this. It was felt that human capital development was important to ensure knowledge transfer, both across APEC health systems and to filter information down to the level of individual clinicians.

IP and regulatory processes are important - strong IP and transparent and timely regulatory and reimbursement processes encourage early launch of life science innovations, with benefits to innovators, patients and health systems. Links to the broader health policy environment also impact on our goals for health services. For example, the provision of accessible information to patients is important, as is making sure physicians are informed about new innovations. The way budgets are set, and encouraging policymakers to consider spending in a whole-systems sense is also important (i.e. not to compartmentalize budgets, without making links between investment in one part of the health system and savings in another). Other influences on the health care environment include approaches to the application of evidence-based medicine, as well as the need to distinguish between short-term cost containment (often damaging to innovation) and long term sustainability. Within the APEC economies, the group considered there was a need to recognize that these principles apply to traditional (e.g. herbal and complementary) therapies. The group also proposes that APEC economies consider the portability of public health insurance as one operating principle.

APPENDIX VI: Example of draft LSIF Readiness Assessment Template (substance of template awaits endorsement of the strategic plan)

LIFE SCIENCES INNOVATION FORUM READINESS ASSESSMENT TEMPLATE

Competencies for each phase of the life sciences value chain—research, development, manufacturing & marketing, and health services—are enumerated below. Through investigation and discussion, the facilitators will help each pilot economy determine their current status and the capacity building needs to reach the target.

Goal:

To conduct an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

Summary Report on the GCG Meeting

By

Professor Dr.Pakdee Pothisiri
Deputy Permanent -Secretary, Ministry of Public Health
Vice-Chairman of the APEC-LSIF
Chairman of LSIF Expert Groups

To

The APEC Life Sciences Innovation Forum Expert Group Meeting
Washington DC, USA
June 11-12, 2004

GCG stands for Global Cooperation Group and was established in March 1999, 9 years after the start of ICH, as a sub-committee of ICH Steering Committee, desiring to establish the link of the ICH with the Non-ICH region. At the beginning, its members are 6 ICH Parties, Public and Private organization from each ICH member; Japan, EU, and the US. The membership also include 2 Observers; the WHO and Health Canada, and the ICH Secretariat.

Starting point of the APEC-LSIF in the GCG was when the GCG invited the Chair of APEC-LSIF to nominate a Permanent Representative of a group to the GCG. Then, the Chair has designated a Vice-Chair Government, Professor Dr.Pakdee Pothisiri, as an Interim Permanent Representative for GCG.

The first participation of the APEC-LSIF was in the GCG Meeting, on 7 June 2004. This June 7 meeting of the GCG was the 1st Meeting of GCG with 5 Non-ICH Regional Harmonization Initiatives participants; namely ASEAN(Association of South East Asia Nations), GCC(Gulf Cooperation Council), PANDRH(Pan American Network for Drug Regulatory Harmonization, SADC(South African Development Community)(by telephone), and APEC. In this first Meeting, both a new Term of Reference or TOR, as well as Mandate of the GCG has been confirmed. It was also in this meeting that each Regional initiative formally presented its activities. In addition, the Non-ICH Regional initiatives identified an Areas of their particular interest. Finally, the Meeting also discussed the GCG next steps.

The GCG-TOR(Term of Reference) is important and has stated clearly the following;

1. The ICH GCG will act as the primary representative of ICH Steering Committee outside the ICH Region.
2. The ICH GCG will invite other non-ICH harmonization initiatives (rather than individual economies) to be “Permanent Representative”.
3. The ICH GCG will invite nomination of “Permanent Representative” to the ICH GCG from those harmonization initiatives that undertake activities meeting criteria established by the ICH GCG and ICH Steering Committee, as following;

The initiative should ;

- Be founded on the principle of harmonizing drug regulation across a defined group of economies
- Be science-based, with clear scientific harmonization objectives

- Be Currently active with meetings/activities regularly scheduled
- Have available, or establish, a mechanism to disseminate information on its activities with the ICH GCG to its member

4. The ICH GCG will open its meeting in the future to the “Permanent Representative” of non-ICH partner initiatives unless, on occasion procedural discussion are required.

To ensure complete transparency of activities, GCG will ;

- Public Summaries of its Meetings and other associated Document on public ICH website
- Establish a ‘mailbox’ on the ICH website to receive questions for the GCG

5. The ICH GCG will use its meeting to identify, with the partner initiatives, topics and process issues associated with harmonization for discussion, collaboration, and potential development into a joint program of activities.

The ICH GCG will meet regularly - times year , at the time of ICH Steering Committee, and at the time of Expert Working Group meeting.

6. On a case by case basis, the ICH GCG will invite other initiatives not meeting the criteria in point 3 above to present to the GCG on a specific topic of interest and relevance to the ICH GCG
7. ICH Steering Committee will be consulted for approval on all proposed ICH GCG activities before they are undertaken.

And the Outcome of the GCG meeting could be summarized, as following;

1. Presentation of *APEC Interim Permanent Representative* on “Draft Criteria for APEC Participation in ICH GCG” has well been accepted and acknowledged by the Meeting.
2. This GCG Meeting was a very fruitful meeting and had allowed a better knowledge and understanding with active participation of non-ICH region initiative.
3. A two-way process of the Meeting had facilitated a flow of information, comments, and proposals.
4. Several Topics of Common Interest were identified.
5. The Meeting defined some actions on specific topics.
6. The Meeting also discussed for a development on exchanges, communication and procedures.
7. Lastly, the Meeting expressed a Positiveness and has welcome the further activities in the following months before the Yokohama meeting, as well.

The ultimate outcome from the GCG meeting was its report and proposal to the ICH Steering Committee was warm acknowledged and adopted. Its Term of Reference has been formally endorsed by the ICH Steering Committee.

APPENDIX VIII: Officers of the Life Sciences Forum and Expert Working Groups

Chair
H.E. Suwit Khunkitti Minister of Natural Resources and the Environment Thailand

Vice-Chairs	
Government & Chair of the Expert Working Groups	Professor Dr.Pakdee Pothisiri Deputy Permanent-Secretary Ministry of Public Health Thailand
Academia	Dr. Peter Sheehan Director Centre for Strategic Economic Studies Victoria University of Technology Australia
Industry	Mr. Richard Smith President Eli Lilly Asian Operations Hong Kong

Discussion Forum Chairs (past and current)	
Research	Dr. Kim Sze Tan (current) Dr. Peter Sheehan
Development	Mr. Michael Ward (current) John Lim
Manufacturing & Marketing	Dr. James McArdle
Health Services	Dr. Edward Bramley-Harker (current) Dr. Frank Lichtenberg

APPENDIX IX: GLOSSARY OF TERMS

APEC	Asia Pacific Economic Cooperation
AP-IMBN	Asia-Pacific International Molecular Biology Network
CMOs	Contract Manufacturing Organizations
CROs	Contract Research Organizations
CTA	Clinical Trials Application
EMA	European Medicines Agency
EMBL	European Molecular Biology Laboratory
EMBO	European Molecular Biology Organization
CHMP	EMA Committee for Medicinal Products for Human Use
GCG	Global Cooperation Group
GCP	Good Clinical Practices
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLP	Good Laboratory Practice
GMPs	Good Manufacturing Practices
GTN	Global Training Network
HRDWG	APEC Human Resources Development Working Group
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH GCG	ICH Global Cooperation Group
IEC	Independent Ethics Committee
IPR	Intellectual Property Rights
IRBs	Institutional Review Boards
ISO	International Organization for Standardization
ISTWG	APEC Industrial Science and Technology Working Group
IT	Information Technology
LSIF	Life Sciences Innovation Forum
Life Science Value Chain	(Research, Development, Manufacturing and Marketing, and Health Services)
MBC	Thailand Medical Biotechnology Center
MRC	Medical Research Council
NIH	National Institutes of Health
NHMRC	National Health and Medical Research Council
OECD	Organisation for Economic Co-operation and Development
PICS	Pharmaceutical Inspection Cooperation Scheme
Progenix	Progenix Research
REDI	Regional Emerging Disease Intervention Center
R&D	Research and Development
TCELS	Thailand Center of Excellence for Life Sciences
TRIPs	Trade-related aspects of intellectual property rights agreement (WTO)
US FDA	United States Food and Drug Administration
Wellcome	The Wellcome Trust
WHO	World Health Organization
WHO GTN	World Health Organization Global Training Network on Vaccine Quality
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

APPENDIX X: GLOSSARY OF INDICATIVE STANDARDS HARMONIZATION INITIATIVES

<p>Agenda for Leadership in Programs for Healthcare Accreditation (ALPHA)</p>	<p>The International Society for Quality in Healthcare (ISQua) initiative ALPHA, (the Agenda for Leadership in Programs for Healthcare Accreditation) looks to ensure global standards for accreditation processes. (http://www.isqua.org.au/isquaPages/Alpha.html)</p>
<p>Global Harmonization Task Force (GHTF)</p>	<p>The Global Harmonization Task Force (GHTF) is a group of representatives from national medical device regulatory authorities and the regulated industry. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members. (www.ghmf.org)</p>
<p>International Conference on Harmonization (ICH)</p>	<p>The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. (www.ich.org)</p>
<p>Trade-related aspects of intellectual property rights agreement (TRIPS)</p>	<p>The WTO's TRIPS Agreement is an attempt to narrow the gaps in the way intellectual property rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. When there are trade disputes over intellectual property rights, the WTO's dispute settlement system is available. (http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm)</p>
<p>World Health Organization Global Training Network</p>	<p>The World Health Organization (Access to Technologies Team (ATT) of the Department of Vaccines and Biologicals) Global Training Network (GTN) consists of several institutions located throughout the world that provide training to achieve quality vaccine production and control. The purpose of the GTN is "to ensure that all vaccines used in national immunization programmes are of assured quality. It provides National Regulatory Authorities (NRA), National Control Laboratories (NCL), and vaccine producers who meet a minimum set of criteria and training. The Network consists of 13 training centres which offer instruction in priority areas using approved syllabi and standardized documentation materials. (www.who.int/vaccines-access/quality/gtn)</p>

APPENDIX XI: Extracts from Ministerial and Leaders Statements concerning Life Sciences
Innovation

2004 APEC Trade Ministers Meeting

MEETING OF APEC MINISTERS RESPONSIBLE FOR TRADE

PUCÓN, CHILE
4 - 5 JUNE 2004

...

“We welcomed the work undertaken by Officials on business related activities, in particular the positive work achieved by business and governmental representatives in the Automotive, Biotechnology, Life Sciences, Chemical and Non Ferrous Metals Dialogues.”

...

“We welcomed the work of APEC's Life Sciences Innovation Forum in promoting global trade and investment in innovative life sciences products and services. We looked forward to reviewing its strategic plan in November.”

2003 LEADERS' DECLARATION

Bangkok Declaration on Partnership for the Future

BANGKOK, THAILAND

21 OCTOBER 2003

...

“We encouraged the Life Sciences Innovation Forum to complete its strategic plan by 2004.”

...

2003 15th APEC Ministerial Meeting

FIFTEENTH APEC MINISTERIAL MEETING

JOINT STATEMENT
SUMMARY OF KEY ISSUES

....

“Ministers welcomed the first Life Sciences Innovation Forum in Phuket, Thailand in August 2003. They took note of the progress in developing the draft Strategic Plan for promoting Life Sciences Innovation and requested that the forum and its expert groups finalize the plan for endorsement in 2004.”

....

FULL JOINT MINISTERIAL MEETING STATEMENT

....

Life Sciences Innovation

“Ministers recognized the importance of life sciences innovation to economic development and the well being of people. They welcomed the first APEC Life Sciences Innovation Forum in Phuket, Thailand in August 2003 and supported the forum’s recommendations to identify economy-specific strengths in life sciences and ways to promote trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation. Ministers took note of the progress in developing the draft Strategic Plan for Promoting Life Sciences Innovation and requested that the forum and its expert groups finalize the plan for endorsement in 2004. As an immediate outcome of the forum, Ministers endorsed an agreement in principle to harmonize quality standards for life science products and services according to international best practices. They requested that the 4th APEC Ministers’ Meeting on Regional Science and Technology Cooperation in New Zealand in 2004 be kept informed of the forum’s progress.”

....

2002 LEADERS' DECLARATION

LOS CABOS, MEXICO

OCTOBER 27, 2002

....

“We called for the establishment of a life-sciences innovation forum comprising government, private sector, and academia representatives to develop a strategic plan for life-sciences 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.”

FOURTEENTH APEC MINISTERIAL MEETING

LOS CABOS, MEXICO

23-24 OCTOBER 2002

JOINT STATEMENT

...

“Ministers also 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' STATEMENT

LOS CABOS, MEXICO

23-24 OCTOBER 2002

...

“We 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.”

...