Asia-Pacific
Economic Cooperation

2013/AMM/011
Agenda Item: 6

LSIF Contributions to the Health Pillar of Sustainable Growth with Equity: Note to Ministers and Leaders

Purpose: Consideration
Submitted by: CTI
Forum Doc. No.: 2013/CSOM/018

APEC
INDONESIA 2013

25th APEC Ministerial Meeting
Bali, Indonesia
4-5 October 2013

LSIF Contributions to the Health Pillar of Sustainable Growth with Equity:
Note to Ministers and Leaders

Honorable Ministers and Leaders:

As Co-Chairs of the APEC Life Sciences Innovation Forum (LSIF) we are honored to present to you for consideration the documents that support the recommendations of the September 24-25 High Level Meeting on Health and the Economy (HLM3). The documents serve as the LSIF contribution to the trade agenda and to the health pillar of the 2013 sustainable growth with equity priority. LSIF again followed the practice of developing trade and innovation work products to implement the LSIF strategic plan, and joined with the Health Working Group on three health and health innovation policy recommendations. The attached documents are summarized below. They are consistent with the tasking statement that resulted from directives from the 2012 AMM and AELM, involve cross-cutting issues, and include innovative approaches to the provision of health care services; ways to facilitate the development of innovations to support/complement a sustainable health care system; ways of ensuring the integrity of the health system supply chain as directed by the 2013 meeting of Ministers Responsible for Trade; and, measures to strengthen the regulatory environment that underpins a sustainable health care system.

Trade Related Recommendations are included in the following documents in Annex A:

(i) Principles for developing the Innovative Health and Life Sciences Sector in APEC economies to support the growth of medical life sciences innovations in the region (LSIF), included in the CTI Annual Report to Ministers.

(ii) Establishment of a Regulatory Sciences Center of Excellence for Multi-Regional Clinical Trials (LSIF) to build capacity in regulatory sciences in the region.

(iii) Implementation of key elements of the Global Medical Products Quality and Supply Chain Integrity Roadmap to kick start the ability of economies to ensure access to safe medicines. The key elements are: establishment of a single point of contact network; product verification and serialization; and, encouraging the closure of illegal internet pharmacies. Key elements are designed to remove the growing availability of spurious, sub-standard, falsified, falsely labeled and counterfeit medical products from the supply chain. (LSIF)

(iv) Establishment of a Regional Training Center to facilitate the commercialization by individual economies of their medical innovations (LSIF).

Cross cutting work products and recommendations developed in cooperation with the HWG are:

Multi-stakeholder collaborations (Annex A), including public private partnerships, and innovative approaches to address key disease cost drivers, including:

(v) Mental health challenges (LSIF/HWG); and
(vi) and (vii) Healthcare Associated Infections (LSIF/HWG)

LSIF also joined with the HWG in Medan on a dialogue on defining the role of and building capacity for safe, quality and effective innovations in traditional/complementary/alternative medicines in health systems, including in primary care and the prevention of disease (Annex A1).

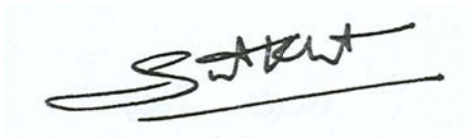
LSIF and HWG continued implementation of the 2011 APEC Non-Communicable Disease Action Plan. Updates from Hong Kong China, Chinese Taipei, and Singapore are included in the APEC document data base.

Finally, LSIF also supported the work of the Small and Medium Enterprises Working Group in a major initiative to drive ethical collaborations to ensure the sustainability of small innovators and support the integrity and sustainability of the medical innovation development process.

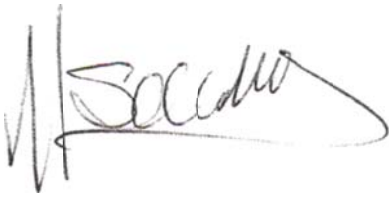
Decision Points

We respectfully request that you endorse the attached documents in Annex A and the recommendations contained therein, welcome and endorse the outcomes of the policy dialogue on Traditional/Complementary/Alternative Medicines as reflected in the outcome of the 3rd High Level Meeting on Health and the Economy (Annex E), and note the continued implementation of the APEC NCD Action Plan.

Sincerely



H.E. Suwit Khunkitti
Chair, LSIF



Dr. Fikry Isaac
Co-Chair, LSIF

Prof. Peter Sheehan
Co-Chair, LSIF

Principles for Developing the Innovative Health and Life Sciences Sector in APEC Economies
Innovative Biopharmaceuticals, Medical Devices, Health Products & Services
Revised September 6

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

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

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

Principle	Justification
Support an Open Economy, Including Free Trade & Investment	
1) Develop and maintain an open economy as defined in the open and competitive markets section of the LSIF Enablers of Investment Checklist that promotes the flow of capital, people, ideas, goods, and services across borders in ways that ensure competition, enhance productivity, and foster growth, keeping in mind public health and safety imperatives.	• An open economy will foster a culture of theoretical and applied scientific research and help grow the pool of top quality scientists, business developers, and entrepreneurs required for the development of an innovative life sciences sector.
2) Promote open investment in life sciences, including by working to remove or reduce restrictions on foreign direct investment in innovative life sciences and taking into consideration domestic regulation and law.	• An open investment environment is a key consideration for businesses looking to invest in the life sciences sector. Year after year, economies with little or no restrictions are able to attract more investment than those with investment restrictions and burdensome regulations. [1]
Encourage Innovative Research & Collaboration	
3) Adopt a framework that supports cooperation and interaction among universities, public research institutions, and companies, including through joint research and development, public-private partnerships, and technology diffusion on mutually agreed terms.	• A framework that supports public-private partnerships and effective technology diffusion from the public to the private sector can accelerate innovation and the commercialization of life sciences innovations.
Provide IP Protection for Innovation	
4) Provide effective and predictable protection and enforcement of intellectual property rights for the full range of	• Creates a legal framework including a strong IP and healthcare environment in which innovators, including small and medium-sized

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

Principle	Justification
innovations in the health and life sciences sector, consistent with multilateral agreements that APEC economies are party to. **5) Ensure that IP laws including patent laws are consistent with WTO rules. Patent protection should last at least 20 years from the date the patent application was filed. The terms and conditions of transfer of technology, production processes, and other proprietary information should be left to the agreement between individual enterprises consistent with WTO rules.** **6) Consistent with multilateral agreements to which that APEC economies are party, ensure the protection of test data required for the approval of life sciences innovations and taking into consideration the complexity of these innovations. Extensive analytical, preclinical, and clinical research tests must be completed before life sciences innovations can be made available to patients.**	businesses, are encouraged to invest in the research, development, and commercialization of life sciences technologies so as to benefit patients. If a framework is well balanced, investors will naturally realize a positive return on their investment, while patients will benefit from a better range of health care options. • Ensuring the integrity of the health and life sciences innovation approval process is important. Test data, which can take several years to generate, typically require substantive commitment in research and development and investment.
Develop Effective & Efficient Regulatory Approval Procedures	
7) Encourage harmonizing regulatory systems of APEC economies consistent with the agreed target of achieving regulatory convergence for medical product approval procedures by 2020. Ensure that regulatory systems are transparent, non-discriminatory, provide due process, and include opportunities for early and meaningful stakeholder engagement.	• APEC Economies are working towards achieving regulatory convergence of medical products by 2020 with the goal of increasing investment in clinical trials and innovative product development and commercialization. • Open and transparent regulatory processes promote innovation, and result in regulations that are more relevant and effective in responding to both regulatory and market needs.
Encourage the Use of Health and Life Sciences Innovations	
8) Promote utilization of innovative health and life sciences by investing in strong healthcare systems.	• The innovative health and life sciences sector will prosper if APEC Economies welcome the introduction of new medical therapies and services into the healthcare system, create value-based markets for such products and services, and build adequate physical infrastructure to ensure their appropriate delivery.

Sources:

APEC, Promoting Effective, Non-discriminatory, and Market-driven Innovation Policy, The Honolulu Declaration: Toward a Seamless Regional Economy (Annex A) (2012).
Available at: http://www.apec.org/Meeting-Papers/Leaders-Declarations/2011/2011_aelm/2011_aelm_annexA.aspx

APEC, 2008 Committee on Trade and Investment Annual Report to Ministers, Life Sciences Innovation Forum Enablers of Investment Checklist (Appendix 7) (2008).
Available at: http://www.apec.org/Groups/Committee-on-Trade-and-Investment/~/media/441C73DB54E746E4835F883BF7154612.ashx

APEC, Addressing the Chronic Disease Challenge in the APEC Region: An Innovative Approach to Collaborative Action (2011).
http://mddb.apec.org/Documents/2011/MM/AMM/11_amm_004.doc

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

Annex A (ii)

Asia-Pacific Economic Cooperation

APEC-AUTM Biotechnology Commercialization Training Center

APEC Research Committee - Companion Project Proposal to the *Roadmap to Innovation*
Vicki Loise, CMP, CAE, Executive Director, Association of University Technology Managers

About AUTM

Since its inception, the Association of University Technology Managers (AUTM) has been a leader in the technology commercialization profession, providing practitioners with networking, education and professional development opportunities, advocating on behalf of the profession, and providing key metrics and other benchmarking data. The association was founded in 1974 as the Society of University Patent Administrators with the objective of addressing a concern that inventions funded by the U.S. government were not being commercialized effectively. Through the years AUTM has grown beyond this single objective and now boasts a global network of more than 3200 members from more than 350 universities, research institutions, teaching hospitals and government agencies as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research in over 30 countries.

AUTM has been delivering high quality professional development to its members and a global audience of practitioners, policy makers, industry, and collaborating organizations for several years. AUTM's standard programs include its annual meeting, regional meetings in the U.S. and in Asia, focused-topic courses delivered in multiple countries and webinars delivered worldwide.

AUTM has developed customized programs for international cooperation to meet the needs of cooperating partners. AUTM uses its global network of technology commercialization offices and professionals to deliver training, build networks, and conduct benchmarking services in partnership with universities, NGOs, and in-country institutions worldwide.

Proposed APEC-AUTM Training Center

In alignment with item #2 in the *Roadmap to Innovation* proposal submitted by Mark Crowell, AUTM is suggesting the development of a multi-national training center to further the knowledge and skills of technology commercialization professionals from APEC member countries. This self-perpetuating training center will include a cadre of trained technology commercialization experts from APEC member countries. These trainers will be well-equipped with AUTM content and further customized content based on feedback collected from APEC member countries about specific needs. The trainers will be available to deliver skills and knowledge development seminars and coursework in the areas of IP management, business development capacity and translational research components. Special efforts will be made to create ongoing support networks via web-based platforms to ensure that the capacity building efforts continue to evolve toward a more sustainable ecosystem.

More specifically, AUTM will create and execute a train-the-trainer program for this Training Center. Technology commercialization professionals with pre-determined and well-established expertise will be recruited to act as trainers. AUTM will facilitate training of these trainers with its own content and continue to build new and customized content based on feedback received by the trainers. These trainers will be available to deliver courses in APEC member countries, at a designated APEC training center housed in an APEC member country (possibly in conjunction with an AUTM member's institution), or through other instructional delivery mechanisms, including web-based offerings. AUTM will ensure up-to-date content is developed and delivered based on learner needs and on well-established worldwide best practices.

An APEC Sustainable Health Care System: Access to Safe Medical Products
Revised September 6, 2013

Ensuring access to safe medicines for patients is a key element of a sustainable health care system. If the global health supply chain is corrupted by substandard, spurious, falsely labeled, falsified and or counterfeit (SSFFC) medical products, the ability of the health system to prevent and manage the health care needs of its people is severely compromised. Costs to health systems rise as death and disability from inadequate or unsafe treatment increase. The availability of SSFFC medical products is increasing. Reports indicate that the global value of SSFFC medical products in global markets could represent an estimated $75B[i] market in 2010. This includes significant penetration in the APEC region through the widespread use of illegal internet pharmacies offering SSFFC medical products for sale, often directly to the consumer.

APEC has acknowledged the importance of health as a driver of economic growth, and the need to secure the global supply chain to ensure patient access to safe medicines. Training projects in 2008 (Asia) and 2009 (Western Hemisphere) for regulators and law enforcement officials have resulted in development of an APEC LSIF Anti-counterfeit Medicines Action Plan to address the problem of counterfeit medicines in the APEC region and to improve the health supply chain (see attached). The Action Plan includes criminal investigations, penalties and legislation, and public awareness and detection initiatives. Importantly, the Action Plan is a living document that is being implemented with ongoing activities and workshops and economies are encouraged to propose projects that help to implement its recommendations.

More recently, the APEC Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee (RHSC) has begun implementing a road map to promote Global Medical Product Quality and Supply Chain integrity. Activities draw on the Action Plan and are focused on cGMP, GDP, product identification, authentication and traceability, detection technologies, internet sales, and the development of a single point of contact (SPOC) network for sharing information, initiating investigations and creating public awareness. Workshops have been held on drug detection technologies (China 2011), and most recently in May 22-23 in Seoul on the development of APEC toolkits focused on public awareness and the development of an APEC Single Point of Contact (SPOC) network for public awareness and enforcement related to SSFFC medical products.

In terms of enforcement, from March to November 2011 customs agencies in APEC partnered in a coordinated effort to target SSFFC medical products in mail and express carrier shipments, resulting in the development of model practices that can guide customs authorities in combating fakes at international mail and express carrier facilities.

On the global front, INTERPOL has partnered with biopharmaceutical companies on a medical product counterfeiting and pharmaceutical crime initiative[1]. Several pharmaceutical companies are also partnering to provide relevant product data to the World Customs Organization (WCO) which operates a secure online tool (Interface Public Members (IPM) online tool) that allows product operational data to be communicated directly to customs officers on the ground. The pilot phase of the World Health Organization's (WHO) Global Surveillance and Monitoring System for counterfeit and falsified medicines will be completed soon. This system will provide a comprehensive tool for incident monitoring and quantification and adverse reactions to counterfeit and falsified medicines.

Ensuring the integrity of the global health supply chain involves multiple processes and actors. Customs and law enforcement authorities, regulators and industry are the key players. Service providers such as distributors and postal/express delivery carriers and internet service providers also are critical to success. Most importantly, there needs to be a strong political commitment.

This year there is a renewed impetus for action. In April 2013, APEC Trade Ministers stated "We look forward to concrete deliverables to assure the quality and integrity of the medical products supply chain".

---

[1] a three year partnership, which was announced in March 2013

2013 Access to Safe Medicines Deliverables

In APEC 2013 consistent with the Trade Ministers' directive, we propose a focus on key activities that promote access to safe medicines as a key element of a sustainable health care system. These are:

1. Support for workshops and training activities under the RHSC Global Medical Products Quality and Supply Chain Integrity road map. These include working on steps to:

   - promote a harmonized standard for product serialization and verification
   - protecting patients from illegal internet pharmacies
   - establishan APEC safe medical products single point of contact (SPOC) network

2. Providing regional support, as appropriate, for global operations to combat SSFFC products
3. Supporting the uptake by member economies of the WCO online IPM tool

In keeping with the Ministerial directive, and to complement efforts to increase regulatory convergence and ensure supply chain integrity under the APEC Anti-counterfeit Medicines Action Plan and the RHSC road map, LSIF supports the establishment of a SPOC network. As a result of the May 22-23 SPOC Workshop in Seoul, agreement was reached to establish a SPOC network and to finalize a SPOC toolkit. APEC economies will aim to identify a SPOC in their economy for an initial meeting of APEC SPOCs in 2014. It was also agreed that a SPOC network would require secure communications infrastructure to enable coordination among the APEC SPOCs.

There are several possible mechanisms that could provide critical technical infrastructure for the APEC SPOC system and information sharing through a secure platform, thereby facilitating coordination and rapid response on cases related to medical product counterfeiting including alerts from regulators. One mechanism is the World Health Organization's Global Surveillance and Monitoring System for counterfeit and falsified medicines. This system captures a great deal of information concerning counterfeit and falsified medical products, links similar incidents, records adverse reactions in patients and permit the quantification and categorization of incidents based on a range of criteria. The pilot phase of this system will be completed soon and system will be more widely very soon. Another mechanism is through INTERPOL, hosted at the INTERPOL Global Innovation Complex to be functional in 2014 in Singapore. Both the WHO and the INTERPOL systems are able to communicate on cases that involve information from non-APEC economies.

Recommended Next Steps

1. Build capacity in APEC economies , with the goal of promoting a harmonized standard for coding product and product verification

2. Encourage the major internet commerce companies (registrars, search engine operators, payment processors, and shippers) in APEC economies to adhere to laws and to adopt voluntary best practices to protect patients from illegal internet pharmacies.

3. Support the establishment of a task force on the development of an APEC SPOC network and facilitate and promote information sharing on SSFFC medical products through global surveillance and monitoring mechanisms.

[i] Mackey, Tim K. et. al., *Dangerous Doses: Fighting Fraud in the Global Medical Supply Chain*, Foreignaffairs.com (May 14, 2012). Available at: http://www.foreignaffairs.com/articles/137634/tim-k-mackey-bryan-a-liang-and-thomas-t-kubic/dangerous-doses.

The establishment of a Regulatory Sciences Center of Excellence for Multi-Regional Clinical Trials (LSIF): Report to the Committee on Trade & Investment

Submitted by Mr. Mike Ward of Health Canada, Chair of the Regulatory Harmonization Steering Committee of the Life Sciences Innovation Forum, August 26, 2013

The Regulatory Harmonization Steering Committee (RHSC) is tasked by APEC Ministers to achieve convergence on regulatory approval procedures for medical products by 2020. Roadmaps to achieve this objective were developed by champion economies. The Roadmap to Promote Multi-Regional Clinical Trials (MRCT), championed by Japan, is highly advanced and has entered the implementation phase. This phase requires focused training in regulatory sciences. The Roadmap's goal is to facilitate MRCTs and the acceptance of MRCT results for review by regulatory authorities.

The RHSC met in Jakarta, 1-2 February 2013, and agreed to explore the establishment of an APEC MRCT Regulatory Science Center of Excellence. The RHSC agreed to conduct a COE pilot training in Q4 2013.

In April 2013, APEC Ministers Responsible for Trade welcomed initiatives to establish a Center of Excellence for regulatory sciences cooperation.

At the RHSC's meeting in Medan, 2-4 July 2013, Japan revised the MRCT roadmap to include the Center of Excellence (CoE). RHSC supported the revised version. In addition, the Ad Hoc Working Group formed to advance the CoE discussed draft curriculum for the CoE Pilot, skill set of possible students, location, timing, faculty, and funding issues. The Ad Hoc Working Group made the following decisions and agreed on the following action items:

Decisions:

- Good support shown for a sampling of topics for the Pilot course curriculum (rather than 1 or 2 topics being presented in-depth).
- Each economy will choose their most appropriate representatives based upon their particular skill set.
- We will aim for 2 students per economy – approximately 40 participants, who will serve as a "focus group" for the Pilot. They will determine the appropriate materials and training modules needed for the CoE. Therefore, the invitation letter should state that this will be an "Expert Group" in hopes of getting representatives with the requisite training and background.
- The Pilot will last 3 days.
- Although students of the CoE Pilot are limited to APEC regulatory authorities, industry will be allowed on the faculty. We want diversity across the APEC region with respect to faculty members.
- The CoE will be located in Singapore at the Duke/NUS (National University of Singapore). This facility has the capability of on-site and virtual learning (e-learning), and will serve as a hub for other training locations.
- The Pilot will be conducted in January/February 2014. Materials will be provided to students 3 months before the class.

Action Items:

- Industry will prepare a mock submission data set that could be used as an example in the Pilot training course.
- Send comments on the draft CoE curriculum to the Chair of the Training Subcommittee once vetted within your respective organizations.
- Send any faculty nominations (name and qualifications) to the Chair of the Training Subcommittee.

To fund the pilot, a concept note was submitted in BMC Round 2 and received in principle approval. A full project proposal was approved by the RHSC and LSIF and submitted to the APEC Secretariat in August. Once approved by the APEC Secretariat the RHSC will transmit the approved version to the LSIF and CTI.

APEC Health Working Group & APEC Life Sciences Innovation Forum
APEC Roundtable Dialogue on Collaborations to Address Mental Health Challenges
3 July 2013 | Medan, Indonesia

Joint Observations & Recommendations

The APEC Health Working Group and APEC Life Sciences Innovation Forum met in Medan, Indonesia on 3 July 2013 for an APEC Roundtable Dialogue on Collaborations to Address Mental Health Challenges. The two groups make the following joint observations and recommendations to APEC Senior Officials with a view to their transmission to APEC Ministers and Leaders as appropriate:

1. Positive mental health is an indispensable component of overall health and wellbeing.

2. Mental health challenges – resulting from brain disorders and deterioration – place a rapidly growing burden on the sustainability of economic growth and prosperity in the region, serving as a leading cause of disability and sometimes resulting in death. These challenges are magnified by the effects of swift economic change and ageing populations. The impact of mental illness on our economies is widespread, resulting in significant economic and social costs that impede the achievement of development goals and threaten the wellness of our communities and workforce. Mental health challenges merit heightened attention by all stakeholders.

3. Obstacles to care and recovery from mental illness drive this growing burden on APEC economies. In particular, they include social stigma, shortages of specialists, access to care, continuity of care and treatment compliance. These obstacles should be addressed through the implementation of awareness building initiatives, enhanced information sharing on lifestyle choices, mental healthcare interventions, and engagement on community-based care.

4. The World Health Organization has called for the integration of mental health into development efforts since 2010.[1] The World Health Organization Comprehensive Mental Health Action Plan 2013-2020, adopted by the World Health Assembly on 24 May 2013, and the ongoing efforts of the WHO Mental Health Gap Action Programme (mhGAP), call for a comprehensive and multi-sectoral approach to address mental health challenges worldwide. The Commonwealth Health Ministers called for expanded economic and social inclusion to address mental health challenges on 19 May 2013 in Geneva, Switzerland.

5. APEC economies are encouraged to implement mental health policies and to include mental health strategies in local and economy-wide health plans. Strategies should integrate global mental health recommendations and cover mental health promotion as well as mental illness prevention, accurate diagnosis, treatment and recovery. APEC economies should encourage research and innovations that improve our understanding of mental illnesses and, in turn, strengthen promotion, prevention, treatment and recovery strategies throughout the life course. There is significant work ahead to alleviate the growing burden of mental illness in the region and success in this effort necessitates heightened focus on community-care and collaboration among all stakeholders, including the private, academic, community, health and non-health public sectors.

6. APEC has an opportunity to lead in the region's implementation of mental health policy plans and recommendations, supporting their translation into concrete results with tangible benefits for economic growth and the wellness of our communities and workplaces. This includes the facilitation of multi-lateral, multi-sectoral, and public-private partnerships built on best and creative practices as well as regional capacity building initiatives that foster information sharing and comprehensive, community-based mental health care options. We believe APEC has a unique advantage to raise awareness and support efforts that reduce social stigma and improve mental health wellness in the workplace.

---

[1] "Mental Health and Development: Integrating Mental Health into All Development Efforts including MDGs", The World Health Organization (WHO) and United Nations Department of Economic and Social Affairs (UNDESA), 12 September 2010

Joint Work Plan on Mental Health

1. The APEC Health Working Group and APEC Life Sciences Innovation Forum propose to jointly develop an "APEC Roadmap to Reduce the Burden of Mental Health Challenges" in 2014 that builds on global and local economy mental health policy plans and recommendations by supporting their translation into concrete, measurable results. Key elements of an APEC Roadmap may include the following on a region-wide and/or individual economy basis:

   A. Regular APEC assessment of the economic and social impact of mental illness on member economies and the development of a regional compendium of best and creative practices in multi-lateral, multi-sectoral, and public-private partnerships demonstrating effective use of prevention, treatment, and recovery strategies throughout the life course in coordination with the assessments of plans and recommendations from other fora.

   B. Sharing of best and innovative practices in multi-sectoral and/or multi-lateral collaboration to:
      - Promote positive mental health, with an emphasis on upstream interventions, to promote well-being as well as to detect and prevent mental illness;
      - Build awareness of mental illness, reduce social stigma, and decrease discrimination
      - Improve surveillance and data collection on the economic and social impact of mental illness on APEC economies, with capability to assess change over time;
      - Mainstream mental health interventions into community and economy-wide health strategies;
      - Train local health and social service professionals in the identification of mental illness and in the use of interventions that promote recovery, thus strengthening community-based mental health care by increasing diagnoses as well as fostering continuity of care and treatment compliance;
      - Encourage all stakeholders to identify strategies and pursue approaches that improve mental health wellness in the workplace as well as in other settings as appropriate; and
      - Encourage research and innovations that improve our understanding of mental illnesses and, in turn, strengthen prevention, treatment, and recovery strategies.

   C. Development of multi-stakeholder capacity building initiatives that foster information sharing and encourage community-based mental health care, including training and community engagement for multi-sector representatives and public health officials.

   D. Regular APEC HWG/LSIF review of the APEC Roadmap and the creation of opportunities for exchange between APEC economies and global thought leaders on effective mental health policy and intervention strategies.

2. To facilitate the drafting of an "APEC Roadmap to Reduce the Regional Burden of Mental Health Challenges", we will develop an APEC project concept note in support of an APEC Workshop on Capacity Building to Address Mental Health Challenges in 2014.

APEC Health Working Group & APEC Life Sciences Innovation Forum
APEC Policy Toolkit for Building Capacity to Prevent and Control Healthcare-Associated Infections
4 July 2013 | Medan, Indonesia

Introduction

Healthcare-associated infections (HAIs) are infections that patients contract in a healthcare facility, from bacteria, viruses and other pathogens which are frequently resistant to antimicrobial treatment.[1] They result in serious clinical, public health, and economic costs, including prolonged hospital stays, long-term disability, preventable deaths, increased antimicrobial resistance, potentially avoidable financial costs to healthcare systems, and high costs for patients and their families. They affect hundreds of millions of patients annually.[2] Fortunately, many HAIs can be prevented through the implementation of effective public policy that requires and incentivizes healthcare facilities to implement comprehensive infection prevention and control practices.

The purpose of this toolkit is to provide policymakers with ideas and a "road map" of how to build and enhance policy frameworks to address HAIs. This document is not intended to be a clinical or technical guide. Rather, it is intended to support those tools by facilitating the development of a robust policy framework to support the sustainable implementation of technical and clinical guidelines and create an environment that enables continued improvement. This document builds upon the recommendations that emerged from the 2012 APEC High-Level Workshop on Reducing the Economic Burden of Healthcare-Associated Infections (HAIs) that was held in Manila, Philippines under the auspices of the APEC Life Sciences Innovation Forum and the APEC Health Working Group.

1) **Consider a comprehensive economy-wide framework or plan to establish an effective infrastructure for infection prevention and control.** Elements of this can include:
    a. Creation or designation of a domestic health agency (or other body) with responsibility for advancing the prevention and control of infectious disease as a public health priority including:
        - Monitoring of organisms of concern, HAIs and infectious disease outbreaks.
        - Management of economy-wide reporting system and process.
        - Assistance with outbreak management.
        - Development and advocacy for sound public health policies at national and state / provincial levels, as appropriate.
        - Development of prevention strategies
        - Research
        - Interface with global infectious disease community
        - Provision of leadership and training to hospitals and other healthcare institutions
    b. Establish an economy-wide infection prevention-HAI advisory committee. This can reside in the agency or body designated body (as above) or another appropriate body. Mechanisms by which various stakeholders can provide input to such an advisory committee can also be developed.

---

[1] HAIs, also referred to as nosocomial infections, are infections that were not present or incubating at the time of admission. They are the most common serious adverse event from healthcare delivery and a leading cause of preventable morbidity and mortality.

[2] B. Allegranzi, et al., "Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis," *Lancet*, 2011 Jan 15; 377(9761):228-41, DOI:10.1016/S0140-6736(10)61458-4.

c. Establish an advisory body responsible for recommending economy-wide plans, goals and guidelines.

d. Some economies have pursued the above policy elements through legislation constructed with input from various stakeholders.

2) **Establish minimum requirements for hospital infection control programs to be implemented at the institutional level with oversight at the economy level.** Examples include:

a. A permanent infection control committee responsible for monitoring, managing and minimizing HAIs.

b. An adequate number of appropriately trained infection control experts and professionals.

c. A program of infection control activities including surveillance for infections and organisms of concern, interventions to prevent infections, identification of opportunities for performance improvement, education and training of healthcare workers and patients.

3) Establish requirements for surveillance and reporting of Healthcare-Associated Infections and organisms of concern at both the economy / regional level and the institutional level.

a. Hospital level data can be used to establish a baseline and performance improvement goals for facility level HAI reduction efforts, track and manage organisms of concern and outbreaks, and improve antibiotic stewardship.

b. Economy and/or regional level data can be used to establish public health goals, track organisms of concern, track and manage outbreaks and understand epidemiologic trends (such as antimicrobial resistance).

c. Factors to consider when developing policies and programs include:

- Determine what data should be collected. Examples of specific pathogens and device-related infections that are the most common are included in the appendix. These and other organisms and sites of infections that are specific to economies should be considered.
- Determine in which types of facilities and in which location within facilities reporting is desired and what data should be reported.
- Determine if reporting should be mandatory. Mandatory reporting may increase reporting rates, although may not be immediately practical in many locations. If reporting is voluntary, consider incentives to encourage reporting. If reporting is mandated, consider linking reporting requirements to other HAI regulations.
- Consider how data will be collected and managed. For example, automated surveillance and management of infection data will improve facility level efforts and is likely necessary to enable infection control efforts at the economy and regional levels.
- Consider whether data will be available to the public. Transparency of HAI data and hospital performance, along with context to enable the public to understand the meaning of the data can be a powerful accelerator performance improvement goals and is a growing trend in many countries.

4) Evaluate and identify financial support

a. Policies and programs will require a predictable level of funding to ensure they are sustainable and effective. Evaluate the levels of funding needed to meet goals in the short-, mid-, and long-term and to support continued improvement. Keep in mind that while there are budgetary impacts in initiating and sustaining HAI prevention and control programs, effective design and implementation will result in enhanced efficiencies and cost-avoidance for a healthcare system.

b. Identify specific funding provisions or potential mechanisms.

c. Consider contingencies for policies and programs in the event that actual funding available is less than planned for periods of time. This can help mitigate the impact of short-term funding gaps on maintaining accomplishments and advances.

d. Financial incentives can be used to accelerate improvement in HAI prevention and control and the consequential benefits derived by health systems. Examples include:

   - Provide targeted assistance to foster improvement in institutions in which there is a leadership commitment to reduce HAIs, but require short-term support to implement necessary infrastructure.
   - Increased reimbursement or subsidies for development of critical institutional level infection control infrastructure, staffing, facility reporting, and / or improvement in key outcomes.

e. Financial disincentives can be used to discourage behaviors at the institutional level that impede progress, taking into account individual regulatory systems and local policy. Examples include:

   - Penalties for non-compliance with reporting requirements.
   - Reductions in reimbursement for infections that would have been avoided if compliance to established policies and programs occurred.

5) Include infection prevention and control in licensure and accreditation standards.

a. Define requirements that promote infection prevention and control (such as adequate policies, leadership, staffing and training) and then ensure that hospital licensure and/or accreditation programs explicitly include these. Concurrently, ensure that confidentiality provisions allow for use of reported data for licensure purposes.

b. Consider opportunities to promote HAI prevention through staff licensure or credentialing. (For example, infection control training.)

c. Ensure that health agencies have authority to inspect institutions as appropriate, including non-licensed and ambulatory settings.

6) Support capacity building, including through training and public-private partnerships.

a. Establish an economy-wide goal of having all healthcare professionals trained in the essential elements of infection control and HAI prevention.

b. Maximize the use and impact of existing educational and training mechanisms, such as requiring infection control training in medical and nursing schools and licensing requirements.

c. Leverage advisory councils to enhance understanding of and compliance with the essential elements in infection control and HAI prevention.

d. Authorize relevant and appropriate health agencies to incorporate training requirements in regulation.

e. Support public-private partnerships as vehicles to pilot innovative and exploratory policies and programs to enhance infection control and prevention.

f. Consider innovative and sustainable funding mechanisms for training and capacity-building.

Appendix 1
Examples of Tools

Following are examples of tools that have been developed and utilized in various APEC economies to support infection prevention and control.

Sample APEC economy frameworks for infection prevention and control:

APEC

- United States Department of Health and Human Services "National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination" (http://www.hhs.gov/ash/initiatives/hai/actionplan/)

- Australian Commission on Safety and Quality in Health Care 'Healthcare Associated Infection' website (http://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/)

Global and Regional frameworks for infection prevention and control:

- World Health Organization Clean Care is Safer Care (http://www.who.int/gpsc/en/)
- European Union plan on anti-microbial resistance (http://ec.europa.eu/health/antimicrobial_resistance/policy/index_en.htm)
- Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections (http://www.europolitics.info/pdf/gratuit_en/324567-en.pdf)
- European MedTech Toolkit on HAIs: http://www.edma-ivd.eu/pressrelease-full?kind=pr&pr=105

Examples of APEC economy commissions and advisory committees on healthcare-associated infections:

- United States Centers for Disease Control (CDC) Healthcare Infection Control Practices Advisory Committee (HICPAC). HICPAC is a federal advisory committee assembled to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare setting. (http://www.cdc.gov/hicpac)
- Australian Clinical Excellence Commission program on HAIs. (http://www.cec.health.nsw.gov.au/programs/hai)

Appendix 2
Examples of the Most Prevalent Healthcare-Associated Infections
Pathogen-specific and Medical Device-Related

The following list briefly summarizes some of the most prevalent HAIs. This list should not be considered exhaustive and each economy should evaluate organisms that are most relevant and prevalent in respective regions.

Pathogen-specific

Clostridium difficile
C. difficile infection (CDI) is caused by toxin-producing strains of the *C*. *difficile* bacteria in the intestine. Antibiotics kill many of the normal gastrointestinal bacteria allowing toxigenic *C. difficile* to grow unchecked which can then cause *C. difficile* infection (CDI). Symptoms of CDI can include severe diarrhea, nausea, abdominal pain, loss of appetite, dehydration, fever, bowel inflammation and in its worse cases, colonic perforation, sepsis, and death. In addition to the adverse health effects of CDI infections, they lead to excess costs. One estimate in the United Kingdom is that each case costs the National Health Service between USD $9,000 and $11,200, which translates to up to $486 million per year.[i]

Methicillin-resistant *Staphylococcus aureus* (MRSA)
Methicillin-resistant *Staphylococcus aureus* (MRSA) is a particularly prevalent organism causing HAIs. People can be colonized with MRSA but show no sign of clinical infection. MRSA carriers can serve as a source of MRSA that can be passed along to vulnerable populations in the hospital or to healthcare professionals who then transmit it to those in their care. In the hospital, colonization and infection with MRSA is often acquired during or after surgery or by patients in the ICU, and can lead to systemic infections in the bloodstream, hospital-acquired pneumonia, surgical site infection and other infections, all of which are difficult to treat.

Multi-drug resistant gram-negative bacilli
Gram-negative bacteria that are resistant to many antibiotics are being increasingly identified as pathogens causing healthcare-associated infections worldwide.[3] A few of the most problematic pathogens are noted below:

- ***Acinetobacter baumannii***
  Antibiotic-resistant *Acinetobacter baumannii* is an increasing source of healthcare-associated infections in many regions of the world.[ii] Outbreaks of acinetobacter infections typically occur in intensive care units and healthcare settings housing very ill patients and rarely occur outside of healthcare settings. The bacterium may cause a variety of infections, ranging from pneumonia to serious bloodstream or wound infections, and the symptoms vary depending on the site of the infection. Colonization may also occur in vulnerable hospitalized patient without causing infection or symptoms. The site of colonization may be the gastrointestinal tract, tracheostomy sites or open wounds. Although acinetobacter poses very little risk to healthy people, hospitalized patients, especially very ill patients on a ventilator, those with a prolonged hospital stay, or those who have open wounds are at greater risk for acinetobacter infection. Acinetobacter is spread the same way that MRSA is spread: via person-to-person contact, on the hands of healthcare workers or contact with contaminated surfaces. Because Acinetobacter may survive in the environment for several days, careful attention to infection control procedures, such as hand hygiene and environmental cleaning, is imperative to reduce the risk of transmission. These bacteria are the most common cause of HAI in China and are a growing problem in Australia and New Zealand.[iii]

- **Extended-spectrum Beta-Lactamase (ESBL)- producing bacteria**
  ESBL-producing bacteria are different from other superbugs, because “ESBL” does not refer to one specific kind of bacteria. ESBLs are proteins that are produced by a large spectrum of genes

[3] “Gram-negative” and “gram-positive” are classifications of bacteria based on their cell wall structure and how they respond to a staining process used in analysis.

found in various gram-negative bacilli. These proteins confer resistance to many antimicrobials. ESBL-producing gram-negative bacilli have been reported from all parts of the world. However, prevalence varies widely because it is difficult to detect ESBL production and because testing and reporting are inconsistent. The most common ESBL-producing bacteria are *E. coli* and Klebsiella species which can cause many kinds of HAIs, such as bloodstream infections, urinary tract infections (UTIs) and surgical site infections. Treatment of infections due to gram-negative bacilli with ESBLs is very challenging and patients may experience a delay in appropriate treatment because the antimicrobial resistance is not identified correctly. Delays in treatment may lead to extended and costly hospital stays as well as death.

- ***Klebsiella pneumoniae* Carbapenamase *(KPC)***

Klebsiella pneumoniae carbapenamase is an enzyme that confers resistance to the carbapenam class of antibiotics. This is significant because carbapenam antibiotics are often the drug of last resort for infections that don't respond to other treatments. The gene responsible for this enzyme was first found in *Klebsiella pneumoniae* but has since been identified in *E. coli* as well. KPC-containing organisms have been documented to cause a wide range of healthcare-associated infections, including pneumonia, bloodstream infections, wound or surgical site infections, and meningitis. In healthcare settings, patients at risk for infections due to KPC-containing organisms are similar to those at risk for infections due to ESBL-producing organisms and multidrug resistant *Acinetobacter baumannii*. Healthy people usually do not get infections due to KPC-containing organisms. Organisms containing KPC genes can be transmitted in the healthcare setting via direct person to person contact, on the hands of healthcare workers, and contact with contaminated environments in the same way as multidrug resistance *Acinetobacter baumannii* and MRSA

- **Vancomycin-resistant *Enterococcus* (VRE)**

HAIs caused by vancomycin-resistant enterococci are increasingly common and difficult to treat. Enterococci are bacteria that are normally present in the human intestines. Vancomycin-resistant enterococci are, as the name suggests, resistant to vancomycin and many other antibiotics, leaving patients infected with VRE with few treatment options. As with MRSA, patients may become colonized with VRE, but may show no signs of clinical infection. Ultimately, some of these carriers will be at risk of infection from VRE, particularly if their immune systems are weakened from cancer or cancer treatments or following surgery. Symptoms from VRE infection are related to the type of infection that the pathogen causes which include sepsis, bloodstream, urinary tract and surgical site infections.

Medical Device-related

Catheter-Related Bloodstream Infections (CR-BSI)

A catheter-related bloodstream infection (CR-BSI) occurs when a patient develops a bloodstream infection with the site of the infection being an intravascular catheter. This may happen when bacteria or fungus grow in or around the catheter and spread to the patient's bloodstream. When these infections are associated with central vascular catheters they are called central-line associated bloodstream infections (CLABSI). CLABSI account for the majority of BSI in the healthcare setting and the attributable mortality of CLABSI is estimated to be between 12% - 25%. It has been shown that a coordinated infection control approach which includes hand hygiene, appropriate skin preparation and catheter line care, and removal of lines when they are no longer needed can significantly impact the occurrence of these HAIs.

Hospital-Acquired Pneumonia (HAP) / Ventilator-Associated Pneumonia (VAP)

HAP is defined as pneumonia that occurs 48 hours or more after admission and that was not incubating at the time of admission. VAP refers to pneumonia that occurs more than 48 hours after naso- or endotracheal intubation.

HAP is the second most common HAI in the United States. There are 300,000 cases of HAP annually, and it carries an associated mortality rate of 30% to 70%.[iv] It is difficult to determine the fraction of patients with HAP whose mortality is directly attributable to their pneumonia (the attributable mortality), but this rate is estimated to be between 27% and 50%. HAP lengthens the hospital stay and is associated with a higher cost of medical care. It is the most common infection occurring in patients requiring care in an intensive care unit (ICU). This increased incidence is because patients located in

an ICU often require mechanical ventilation, and mechanically ventilated patients are more likely to develop HAP than non-ventilated patients.[v]

Surgical Site Infection (SSI)

A surgical site infection (SSI) is an infection that develops within 30 days after an operation or within one year if an implant was placed and the infection appears to be related to the surgery.[vi] Research suggests that 26% - 54% of SSIs are preventable through comprehensive pre-operative and intra-operative management of skin antisepsis, prophylactic antimicrobials, and attention to other measures as outlined by the Surgical Care Improvement Project (SCIP).[vii]

Catheter-associated Urinary Tract Infections (CAUTI)

A urinary tract infection (UTI) is an infection involving any part of the urinary system, including the urethra, bladder, ureters, and kidneys. Among UTIs acquired in the hospital, approximately 75% are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine. These are referred to as catheter-associated urinary tract infections (CAUTIs). The most important risk factor for developing a CAUTI is prolonged use of the urinary catheter.[viii] CAUTIs comprise 40% of all institutionally acquired infections.[ix]

Transfusion Transmitted Infections (TTIs)

Transfusion Transmitted Infections (TTIs**)** occur when an infected unit of donated blood is transfused to a patient. Globally, annual unsafe blood transfusions are estimated to have been responsible for up to 16 million new HBV infections, 5 million new HCV infections, and 160,000 cases of HIV infections. Millions of people worldwide rely on donations of blood and blood-derived products each year. Since the components of a single unit of blood may be used in 1- 4 recipients, there is the potential for one infected blood unit to reach multiple patients. According to the WHO, "Screening for TTIs to exclude blood donations at risk of transmitting infection from donors to recipients is a critical part of the process of ensuring that transfusions are as safe as possible." International screening standards include testing blood with ELISA (serology) and Nucleic Acid Technology (NAT). ELISA performs indirect identification of a pathogen via donor's immune response (antibody) or detection of antigens produced by pathogen. NAT looks for the genetic material of disease causing organisms, and can detect infections in donated blood earlier than routine serology tests. When used in parallel, this testing protocol can ensure the safest possible blood reaches patients.

---

[i] Katikireddi, V., "UK launches inquiry into *Clostridium difficile* outbreak, " *CMAJ*, July 19, 2005; 173:138, DOI:10.1503/cmaj.050771.

[ii] Andrew Pollack, "Rising Threat of Infections Unfazed by Antibiotics," *New York Times*, accessed February 27, 2010, http://www.nytimes.com/2010/02/27/business/27germ.html?_r=1&scp=2&sq=resistant&st=nyt

[iii] United States Centers for Disease Control and Prevention, "Healthcare-associated Infections (HAIs) - *Acinetobacter* in Healthcare Settings," last modified November 24, 2010, http://www.cdc.gov/HAI/organisms/acinetobacter.html

[iv] McEachern R, Campbell GD Jr., "Hospital-acquired pneumonia: Epidemiology, etiology, and treatment," *Infect Dis Clin North Am*. 1998, 12: 761-779.

Editorial: Improving blood safety worldwide *Lancet* (2007) 370:361

[v] http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/infectious-disease/health-care-associated-pneumonia/

[vi] Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, "The Hospital Infection Control Practices Advisory Committee. Guideline for the prevention of surgical site infection, 1999," *Infect Control Hosp Epidemiol*, 1999;20:247-280.

[vii] The Surgical Care Improvement Project (SCIP), http://www.qualitynet.org/dcs/ContentServer?c=MQParents&pagename=Medqic/Content/ParentShellTemplate&cid=1122904930422&parentName=Topic

[viii] United States Center for Disease Control and Prevention, "Healthcare-associated Infections (HAIs) - Catheter-associated Urinary Tract Infections (CAUTI)," last updated January 20, 2011, http://www.cdc.gov/HAI/ca_uti/uti.html

[ix] Burt CW, Schappert SM, "Ambulatory care visits to physician offices, hospital outpatient departments, and emergency departments: United States, 1999– 2000, " National Center for Health Statistics. Vital Health Stat 13 (157). 2004.

APEC Health Working Group & APEC Life Sciences Innovation Forum
Medan Principles for Public-Private Partnerships in Infection Prevention & Control

4 July 2013 │ Medan, Indonesia

At their September 2012 meeting in Vladivostok, Russia, APEC ministers welcomed work in APEC to address the economic and public health burden of healthcare-associated infections and encouraged APEC Member Economies to enhance work with stakeholders in order to reduce the incidence of infections in healthcare settings. APEC member economies recognize that collaboration among government agencies, professional and scientific societies, academic and research institutions and private sector entities has been integral to advances in infection prevention and control in the Asia Pacific region to date. Effective partnerships leverage the expertise of each party and can return results that are more impactful and more efficient than if each party operated separately. At the July 2012 APEC High Level Workshop on Reducing the Economic Burden of HAIs in Manila, the Philippines, APEC economies recognized that frameworks and guidelines are needed to support to development of infection prevention and control partnerships at the institutional, local, and government levels within APEC Member Economies.

As a first step in this effort, the APEC Health Working Group and the APEC Life Sciences Innovation Forum have developed the *APEC Medan Principles for Public-Private Partnerships in Infection Prevention & Control*. The Medan Principles draw on existing APEC guidances, including the APEC principles for public-private partnerships for disaster resilience,[1] and the APEC Kuala Lumpur (KL) Principles for Medical Device Sector Codes of Business Ethics. [2]

Public-Private Partnerships (PPPs) in infection prevention and control should be conducted in accordance with the following 16 guiding principles:

1. **Integrity:** Parties to PPPs should deal honestly, truthfully, and fairly with all parties.

2. **Independence:** Private sector interactions with healthcare providers (HCPs) and governments in a PPP should not skew the HCP's medical decision making from the best interests of the patient. Collaborative interactions between the private sector, government officials and HCPs involved in PPPs should preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.

3. **Appropriateness:** PPP arrangements should conform to proper commercial standards, and are accurate and free from corrupt purposes. Private sector partners should not provide entertainment and recreation to HCPs or government officials as an inappropriate inducement. Private sector contributions to PPPs should not be a means to privately benefit a HCP or influence government policy. Free products should not be used as a means of inappropriate inducement in a PPP. However, the private sector may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

4. **Transparency:** PPP participants should be open regarding significant financial relationships between the private sector and HCPs. PPPs should support fair competition and participants should not engage in collusive behavior or practices that could inappropriately influence the prices of products or services.

5. **Designed to Advance Healthcare:** Private sector relationships with HCPs and governments in PPPs should be intended to advance patient care. PPP agreements between the private sector, governments and HCPs should support research and development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. PPP agreements should not be used as a means of inappropriate inducement.

---

[1] Public-Private Partnerships and Disaster Resilience, Report from APEC Workshop on Public Private Partnerships and Disaster Resilience, Bangkok 24-29 August, 2010

[2] The Kuala Lumpur Principles Medical Device Sector Codes of Ethics, 2011. http://www.apec.org/en/Press/News-Releases/2011/~/media/Files/Press/NewsRelease/2011/The%20Kuala%20Lumpur%20Principles.ashx

6. **Adequate staffing and funding.** PPPs should be fully funded and staffed. Rather than rely on good will or personality based leadership, long term success is developed through consistent and adequate funding, dedicated staff and the resources needed to build and grow the partnership.

7. **Shared responsibilities and clearly assigned roles:** PPPs should be based on shared responsibilities and clearly assigned roles and tasks that contribute to the goal of building capacity to improve infection prevention and control.

8. **Achieve synergies through collective contributions.** A strength of PPPs is achieving synergistic results that are greater than the sum of the parts. Each partner can contribute unique strengths that fill gaps in other partners' knowledge or resource bases. Partners should work together to improve their collective scientific, technical and management competencies, and expertise to support long-term efforts to build capacity to improve infection prevention and control. Partners should not be engaged in the PPP merely as a source of funding for the other partners' activities.

9. **Further Education.** Private sector support of HCPs' education in a PPP, for example through support to third-party educational programs and educational grants, should preserve the independence of medical education and should not be used as a means of inappropriate inducement.

10. **Training.** The private sector may provide training of HCPs and government officials on the deployment, use and application of products and services to facilitate the safe and effective use of medical innovations in PPPs.

11. **Embrace innovation:** PPPs aiming to build infection control capacity and capabilities in an economy should be understood as learning journeys. PPPs should be open to new and innovative ways of working together and allow for flexibility to adapt the partnership as it evolves.

12. **Flexibility.** Partnerships may contain similar characteristics, but they should allow for flexibility in their approach to better incorporate regional opportunities, risks, political situations and other unique features. This tailored approach will enable partnerships to focus resources and funding where the most impact can be made.

13. **Process for assessing effectiveness.** A process for assessing the effectiveness of partnerships should be developed and both parties understand and agree on the mechanisms.

14. **Role of women and minorities.** The role of women and minorities in the delivery of healthcare in APEC economies and in the maintenance of healthy communities should be encouraged in infection control PPPs.

15. **Incentives.** Governments should explore well-designed incentives for the development of PPPs with a focus on rewarding results. Beneficiaries of incentives can be any or all parties involved, including state and local governments, NGOs, or private sector partners.

16. **Apply Lessons Learned**. Governments should leverage positive results from PPPs. For example, best practices learned through can be applied to broader national plans and policy. Additionally, successful elements of programs can be integrated into economy-wide programs.

Policy Dialogue

Widespread Use of Traditional Medicine Products as Modality to Address Health Problems in the Future

Medan, July 3rd, 2013

POSSIBLE RECOMMENDATIONS

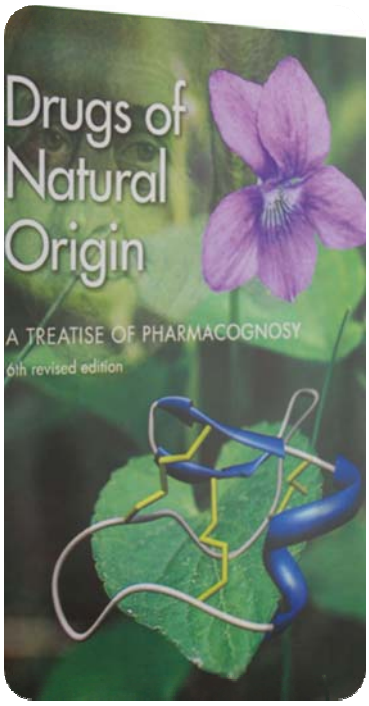
Contents

Background

Health System Capacity and Traditional Medicine

In this first decade of the 21st century, immense advances in human well-being coexist with extreme deprivation in many parts of the world. In-equities in availability, accessibility and affordability of health care have increased, between as well as within populations the world over. Access to appropriate healthcare is increasingly being acknowledged as a human right through international instruments such as the United Nations Human Rights Commission, the Millennium Development Goals (MDGs) and the World Health Organization (WHO).

There has been a growing interest in Traditional Medicine/Complementary and Alternative Medicine (TCAM) and their relevance to public health both in developed and developing countries. Diversity, flexibility, easy accessibility, broad continuing acceptance in developing countries and increasing popularity in developed countries, relative low cost, low levels of technological input, relative low side effects and growing economic importance are some of the positive features of traditional medicine (WHO 2002). In this context, there is a critical need to mainstream traditional medicine into public health care to achieve the objective of improved access to health care facilities. However, evidence suggests a disparity between personal choices the public make in terms of integration of different medical systems and the TCAM policy formulation and their implementation. According to WHO, some of the major policy challenges include wide diversity safety, efficacy, quality and rational use of traditional medicine.



Whereas there is wide diversity at a practical level, a basic philosophical underpinning of all such knowledge systems is their acceptance of a shared worldview which is an inherent relationship and sharing of key elements between the macro and microcosm-the outside universe and a living being. Few other common dimensions are ecological centeredness, focus on ‘non-material' or ‘non-physical' dimensions, and a comprehensive approach to health, keeping in mind physical, mental, social, emotional, spiritual, ecological factors in wellbeing.

However, it is only 66 countries out of 213 WHO member states have traditional medicine policies, while around 43 states have some kind of legislation and 20 member states are in the process of establishing some regulatory policies (Bodeker et al. 2007). Key elements suggested in a national policy are definition of TCAM, definition of governments’ role in developing TCAM, provision of safety and quality assurance for therapies and products, legislation relating to TCAM providers, provision of education and training, promotion of proper/rational use, provision of capacity building for human resources including allocation of financial resources, provision of coverage by public health insurance and consideration of intellectual property right issues.

In many developed countries though there are strict regulations for usage of traditional medicine, there is a growing trend of traditional medicine use in the guise of health supplements' and spas. Increased adoption of national policies would facilitate creation of internationally accepted norms and standards for research into safety and efficacy of TCAM, rational use, sustainable usage of natural resources and protection and equitable use of knowledge of traditional medicine.

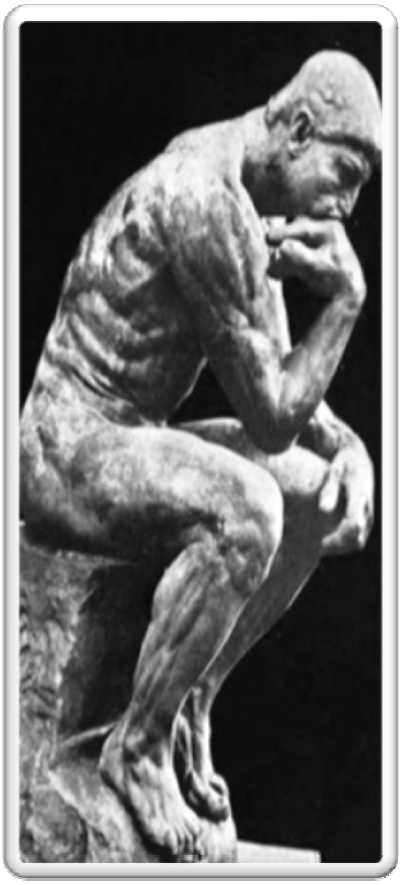
Socio-economic Impact of Optimizing Traditional Medicine

World market of herbal medicine based on traditional medicine is estimated at US $60 billion (WHO 2002) and it is steadily growing. The global wellness spa industry which is vastly based on TCAM is valued at $255 billion annually (Cohen and Bodeker 2008). Many of the major modern drugs such as quinine, salicylic acid, artemisinin have been discovered from folk knowledge. According to NAPRALERT database of the University of Illinois, Chicago, 74%of the 119 pure compound based modern drugs derived from plants have been based on leads provided by traditional medical knowledge and the modern applications are similar to the traditional ones (Farnsworth 1988). As the economic importance of traditional knowledge and medicinal plants based products and services are growing they provide employment opportunities to various sections of people. At the same time, it raises concerns about availability of medicinal plants, increasing costs of herbal products in domestic market especially for marginalized population and dilution of classical practices.

TCAM sector is receiving increasing policy support now from multilateral organizations. In a United Nations Environment Program (UNEP) conceptual framework on poverty and ecosystem, ability to use traditional medicine is one of the 10 resources of wellbeing (Janska 200). The Convention on International Tradein Endangered Species of Flora and Fauna (CITES) under UNEP has promoted sustainable use of natural resources by monitoring trade of endangered species of flora and fauna. The Food and Agriculture Organization (FAO) has developed many policy resources on non-timber forest produce including medicinal plants pertinent to policy, conservation and research. The UN Conference on Trade and Development (UNCTAD) is involved in protection of traditional knowledge and also promoting trade and development

opportunities for developing countries through traditional medicine. The UN Industrial Development Organization (UNIDO) has been recommending support for industrial use of medicinal plants, improved technologies for standardization, and supporting capacities of member countries. The World Intellectual Property Organization (WIPO) has supported initiatives for IPR protection of traditional medical knowledge.

Points of view from the Dialogue



From honorable presenters during this Policy Dialogue and its interactive enriching discussions, several points are worth to be mentioned, as follows:

1. Traditional medicine is an approach for healthy living, that is affordable, available, and as a part of indigenous health beliefs of local culture. Furthermore, the trend in global market is steadily increasing, with currently estimated of 60 billion USD. It is therefore this policy dialogue is important for combining the approach with modern medicine (Goodenow 2013: Opening Speech of this Policy Dialogue).
2. The Vice Governor of North Sumatera is emphasizing traditional medicine to strengthen each APEC's economic members, including Indonesia's utilizing biodiversity rich ecosystem for strengthening traditional medicine usability within healthcare system (Vice Governor of North Sumatera: Opening Speech of this Policy Dialogue).
3. Indonesia has started a very popular program, called "Jamu Scientification", as an approach to provide scientific basis for herbal medicine (***jamu***, in Indonesian) and to popularize the use and application of jamu in the healthcare system. (Director General of National Health Research and Development of MoH on his Keynote Presentation, 2013). The frameworks used are: (a) developing knowledge base and system for jamu practices; (b) promote safety, efficacy and quality of jamu; and (d) improve access of rational use of jamu.
4. In less developing countries, including in Indonesia, there is a need to improve health care merely because of increasing global health risks

and advancement of modern medical and/health technology. On the other hand, there are traditional medicine approaches in each country that can be a part, and synergize in modern healthcare system. In some APEC's economic members, the synergizing efforts of traditional medicine into modern health care are spanned more that 3-4 decades.

5. In the same logic, an effort to establish health human resource for traditional medicine should be done gradually. Indonesia has long experience of educating traditional healer at Diploma-3 and Diploma-4 levels (equal to bachelor degree). The scientific and academics legacy of Traditional Medical Doctor (TMD) is then can be synergized with conventional MDs.
6. Each APEC's economic member has a long list of biodiversity richness. In Indonesia, there is estimated 30,000 species, and only one-thirtieth has been developed as traditional medicine. As comparison, in Taiwan, for example, there are estimated 22,000 registered herbal medicines, with currently more than one hundred companies producing herbal medicine already applying GMP principles. These situations affecting to one-third people in the country to use combination of use traditional medicine and modern western healthcare. However, the big challenge is related to the aspect of safety, effectiveness and quality of traditional medicine. The WHO has long term strategies, i.e., 2014-2023 strategies to solve and deal with these issues, mainly facilitating and supporting each WHO's member for developing each country's traditional medicine capacities with focuses on (a) developing knowledge base of traditional medicine; (b) integrating traditional medicine into healthcare system; (c) promote safety, efficacy and quality of traditional medicine; and (d) improve access of rational use of it.

7. With this small part of exploration in many APEC's economic members, still, the market is huge and increasing. It is estimated that the global market will be doubled from 48 billion USD in 2012 to 2015.
8. The expansion of traditional medicine within healthcare system can be achieved with strong policies and programming in healthcare facilities/provision, and medical payment schemes. This policy should be supported by health financial mobilization effort, through for example, universal coverage framework.
9. Evaluating the efficacy, safety and quality of traditional medicine use, as a part of post market strategies, should be supported by health information system.

Feasible Principles

The people have the right and duty to participate individually and collectively in the planning and implementation of their health care, and the primary health care relies on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners, suitably trained socially and technically to work as a health team and to respond to health needs of the community.

Harmonization and alignment of legislative frameworks and regulatory practices will be promoted to facilitate collaboration. This will include the leveraging of existing international standards and guidelines (e.g., WHO), as appropriate.

Capacity building and the sharing of technical expertise will be supported, building on existing initiatives, enablers, and structures, as appropriate.

Traditional medicine, as one of these sources of primary health care services, could contribute to improved health outcomes, including those in the Millennium Development Goals. Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (WHO).

As the various traditions of TCAM have their roots in many different cultures and have only recently been investigated scientifically, it must be recognized that knowledge about TCAM is apt to be still perpetuated by oral tradition and

found in anecdotal observations rather than in systematic laboratory and clinical studies that have been published in the scientific literature. Furthermore, it must also be recognized that while some publications on TCAM may not meet the stringent requirements of international peer-reviewed journals, they may still provide potentially useful observations and ideas for further study. Therefore, a thorough literature survey should be the starting point for every serious effort in TCAM research.

Holism is a key element of all systems of traditional medicine. Therefore, when reviewing the literature on traditional medicine (both herbal medicines and traditional procedure-based therapies), the theories and concepts of the individual practice of traditional medicine, as well as the cultural background of those involved, must be taken into account. Even though, in conventional medicine, holism approach should be applied as well

Research approach for traditional medicine should be started from wide usability of the traditional medicine in the community, using mixed method of research including qualitative studies combine with clinical quantitative approaches for obtaining efficacy and safety information of traditional medicine. As traditional medicines are has been practiced and used in community reverse pharmacology or efficacy driven clinical trials can be used as one of the methods of obtaining efficacy and safety information as appropriate.

Pre and control market supportive government policies are needed to promote access to safe, quality and efficacious traditional and alternative medicine and therapies, and to expand rational use of traditional medicine.

Realizing that, as a consequence of the loss of plant diversity around-the world, many of the plants that provide traditional and modern drugs are threatened with extinction endorse the call for international cooperation and coordination to establish programs for the conservation of medicinal plants, to ensure that adequate quantities are available for future generations.

Training in many aspect of traditional medicine, including traditional healers and traditional medical doctors (TMD), modern medicine such as physiology, phytochemistry, pharmacology and others, which contribute to the rational use of TCAM, will help to build a core of competent and traditional medicine practitioners and researchers for the study of TCAM. The productivity of such profession and researchers will be enhanced by workshops, seminars, lectures, study tours, and scientific exchange programs with colleagues from other countries.

Proposed Recommendations for individual APEC member economies (as appropriate)

Medan, Republic of Indonesia, July 3, 2013 – APEC Health Working Group (HWG) and Life Sciences Innovation Forum (LSIF) on Policy Dialogue on the Development of Medicinal Plant and Traditional Medicine has delivered set of potential recommendations, as follows:

1. Leaders reaffirm the commitment to develop TCAM for the purpose of people's welfare, health, and productivity according to individual member economies' situation.

2. Leaders recognize that effective governance at all levels (national and sub-national), appropriate financing, adequate provision of skilled health professionals, including traditional healers and other human resources for health (HRH) are critical component for success.

3. Leaders commit to work towards the *Widespread Use of Traditional Medicine Products as Modality to Address Health Problems in the Future* through the following:
    a. Respect, preserve and communicate, as appropriate, the knowledge of traditional medicine, treatments and practices, appropriately based on the circumstances in each country, and on evidence of safety, efficacy and quality.
    b. Formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine.

c. Formulate national policies, regulations and standards, to promote quality and efficacy of traditional medicine.
d. Consider where appropriate, inclusion of traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and quality.
e. Further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the global strategy and plan of action on public health, innovation and taking into consideration the issue of intellectual property right.
f. Establish systems for the qualification, accreditation or licensing of traditional medicine practitioners and facilitate traditional medicine practitioners to upgrade their knowledge and skill in collaboration with relevant health providers, on the basis of traditions and customs of indigenous peoples and communities.
g. Strengthen communication between conventional and traditional medicine providers and, where appropriate, establishing appropriate training programs with content related to traditional medicine for health professionals, medical students and relevant researchers
h. Strengthen the cooperation among the economies in sharing knowledge and practices of traditional medicine and exchanging training programs on traditional medicine, consistent with national legislation and relevant international obligations.

i. Promote the conservation and cultivation of medicinal plant in order to provide the sustainability of supply of raw material using the local herbs that empirically proven, as appropriate.

4. Leaders agree on having an investment at national level in terms of research and development, innovations, and integration of TCAM into national health system with consideration of efficacy, safety, and quality.

5. Leaders build on three pillars as a strong foundation in strengthening traditional and alternative medicine by strengthening Public-Private Partnership, synergizing and integrating TCAM in health care system, and involving Communities, according to individual economies' needs.