



# HEALTH IN APEC

Creating economic prosperity through strategic health care investments and enabling environments for business



Prepared by the National Center for APEC



## KEY TERMS

**ABAC** – APEC Business Advisory Council

**AHC** – APEC Harmonization Center

**AHWP** – Asian Harmonization Working Party

**APEC** – Asia-Pacific Economic Cooperation

**ASEAN** – Association of Southeast Asian Nations

**CMS** – U.S. Centers for Medicare & Medicaid Services

**CTCS** – Citizen Telecare Service System

**ER** – Emergency Room

**GDP** – Gross Domestic Product

**HAI** – Healthcare-Associated Infection

**HIT** – Health Information Technology

**HLM** – High-Level Meeting

**HWG** – Health Working Group

**ICU** – Intensive Care Unit

**IMDRF** – International Medical Device Regulators Forum

**INICC** – International Nosocomial Infection Control Consortium

**IPR** – Intellectual Property Rights

**LSIF** – Life Sciences Innovation Forum

**MRCT** – Multi-Regional Clinical Trials

**NCD** – Non-Communicable Disease

**OECD** – Organization for Economic Co-operation and Development

**RHSC** – Regulatory Harmonization Steering Committee

**WHO** – World Health Organization

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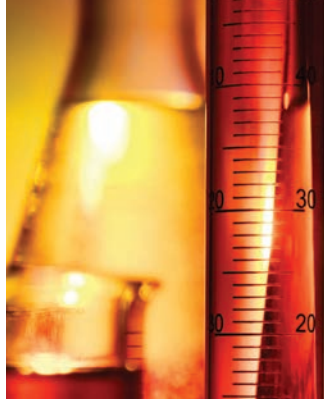
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## SUMMARY

**A**PEC's economies face mounting economic challenges resulting from the continued burden of infectious disease, rapidly aging populations, and exponentially increasing rates of non-communicable disease. Together, these trends are making an impact on the productivity and quality of life of populations across the region, as well as burdening economies with significant health care costs. High-impact investments by governments and businesses in robust health care systems, underpinned by good economic policies and efficient regulatory systems, will be required to ensure that these growing trends do not diminish the Asia-Pacific region's competitiveness. These investments have the potential to generate significant economic returns in the form of increased flows of trade and investment, an innovative and job-producing life sciences sector, significantly reduced care costs, and increased workforce productivity.

Industry is making an important contribution to ongoing efforts to address these challenges by creating and delivering innovative medicines and therapies, making investments in community and employee health programs and by advising governments on trade and economic policies that will improve health care access and delivery. Indeed, the full potential of industry to contribute to the solutions required for these significant challenges can only be realized through good regulatory policies and engagement in robust multisectoral partnerships with substantial long term objectives.

APEC provides an important vehicle for this critical partnership under its mandate to promote trade and investment liberalization, business facilitation, and economic and technical cooperation. Each year it provides a venue for government officials ranging from heads of state, health ministers, and regulators to meet with industry leaders and experts, forming the basis of public-private partnerships that generate meaningful results in the



region. These partnerships and initiatives cover a broad range of important subjects and address a number of complex challenges:

- Hundreds of regulators, experts, and industry representatives have engaged in training and capacity building efforts to promote regulatory convergence in medical products, which are essential for public safety, secure supply chains and the timely delivery of medicines, devices and therapies.
- Close cooperation to manage and prevent non-communicable diseases (NCDs) and healthcare-associated infections (HAIs) is helping economies use resources efficiently to reduce health care costs.
- Measures to promote ethical business practices in the pharmaceutical and medical devices sectors are promoting patient safety and improving the business environment for large

and small firms.

- Officials are exploring how best to leverage health information technology to create efficiencies in health care systems and promote active and healthy aging.

As partnerships have evolved and official participation has increased, health has gained increasing prominence on APEC's agenda. Continued industry engagement coupled with robust participation from officials responsible for trade, finance, and health care policy, will ensure its continued success and further promote economic cooperation and inclusive growth in the region.

# HEALTH: INTEGRAL TO ECONOMIC PROSPERITY

**A**PEC economies face a significant obstacle to sustainable economic growth in the form of a “triple burden” resulting from demographic, economic, and health trends across the region: the first is the continuing high incidence of infectious diseases, such as influenza, malaria, HIV/AIDS, and tuberculosis, which have high human and financial costs as well as the economic and health burdens brought about by otherwise preventable healthcare-associated infections (HAIs) that often occur at significantly higher rates in developing countries. The second is the rapid and widespread increase of non-communicable diseases (NCDs), such as cancer, diabetes, and cardiovascular and respiratory diseases, which are now the source of the most illness and leading cause of death in most APEC economies. NCDs cause significant suffering and are very costly to diagnose and treat; their rise is creating new, unsustainable pressure on health budgets and is exacerbated by increases in lifestyle risk factors (such as obesity, hypertension, and exposure to pollution) in both developing and developed economies. Thirdly, the APEC region’s populations are aging rapidly, which will result in an increased expenditure of resources needed for ongoing care and public pension systems, as well as—in the absence smart policies and solutions that enable productive aging—significantly reduce a population’s social and economic engagement in society and impact the net productivity of workforces. In

combination, the “triple burden” has the potential to create a substantial drag on economic growth.<sup>1</sup>

In response to these challenges and as a result of significant effort from committed stakeholders in governments, industry, and academia, health has gained increasing prominence in APEC’s agenda. Its groundbreaking efforts have created momentum around addressing the social and economic challenges created by health trends in the region by leveraging APEC’s mandate to promote trade, investment, and cooperation in the region. APEC’s diverse member economies and non-binding, consensus-based atmosphere allows for an important evolution of ideas and facilitates substantive cross-sector and intra-governmental conversations and partnerships that otherwise would not happen. The resulting dialogue and exchange sensitizes new audiences to critical health issues, helping finance, commerce, and trade ministries understand the direct and substantial impact health has on every economy’s bottom line in human and economic terms. Further, APEC provides high value as a collaborative platform to complement and enhance work in other exclusively health-focused organizations, such as the World Health Organization (WHO) and

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<sup>1</sup> Paragraph informed by: Peter Sheehan et al., “Investing in the Future: An Assessment of the Returns to Investment in Health Innovation” (framework paper prepared for the APEC Life Science and Innovation Forum VI, Lima, Peru, August 14–15, 2008), [http://www.cfses.com/documents/2008\\_CSES\\_LSIF\\_VI\\_APEC\\_Investing\\_in\\_the\\_Future.pdf](http://www.cfses.com/documents/2008_CSES_LSIF_VI_APEC_Investing_in_the_Future.pdf).

the United Nations. The end result is more effective regional health solutions and policies within each economy and effective strategic partnerships between policy makers and industry.

## THE BUSINESS CASE

Industry is an essential partner in the ongoing efforts to address health and health care challenges that are present in the APEC region. When addressing APEC's first High Level Meeting between Health Ministers and business leaders, U.S. Secretary of Health and Human Services Kathleen Sebelius noted that "Business can...play a unique role in sharing solutions". She added that "Multinational companies are one of our best vehicles for carrying innovative ideas across national lines."<sup>2</sup> Indeed, the private sector is a critical source of foreign direct investment, instrumental in developing the capacity of local industry to innovative and often serves as a key knowledge partner to officials responsible for developing a wide range of policies that are instrumental in shaping their home economy's regulatory, health care, and investment environment. Companies are not only some of the world's most important sources of health tools (vaccines, drugs, diagnostics, devices, and health information technology) and the funding for their continued improvement, but also drivers of efficiency and transparency in regulation, quality, and safety, as well as catalysts for innovation. Simply put, governments cannot address the health challenges of the present and future (nor harness the opportunities) without industry.

<sup>2</sup> Kathleen Sebelius, speech prepared for APEC 2011 Meeting, San Francisco, USA, September 16, 2011, U.S. Department of Health and Human Services, <http://www.hhs.gov/secretary/about/speeches/sp09162011.html>.

**“Companies are able to have important discussions at APEC. APEC’s diversity and the fact that decisions are non-binding are strengths that make it a great forum for tackling hard issues.”**

William Weldon, Former Chairman & Chief Executive Officer, Johnson & Johnson

## BENEFITS FROM STRATEGIC PARTNERSHIPS IN APEC

- Improved health care and medical product safety, quality, and access for patients.
- Reduced risk of market disruptions.
- Support to combat counterfeit medical products.
- Improved care and faster access to high-quality, innovative medical products for patients: regulatory harmonization would lower market barriers for medical products by making it easier to satisfy regulatory requirements in multiple countries and bring innovative therapies to patients faster.
- A common code of ethics for foreign and local firms.
- A pro-innovation environment, supported by regulatory changes that ensure safety and quality while also improving the investment environment for life sciences.



## IMPACT HIGHLIGHT ECONOMY-SPECIFIC GUIDES FOR PROMOTING THEIR LIFE SCIENCES INVESTMENT ENVIRONMENT

Recognizing that innovation doesn't happen spontaneously or automatically, the APEC LSIF's **Enablers of Investment Checklist** serves as a self-assessment tool for policymakers to assess their investment environment for life sciences innovation. Completed by Singapore, Canada, Indonesia, Chinese Taipei, and the United States, the Checklist effectively serves as a guide for promoting research and development of new medical technologies, products, and services. Singapore was the first APEC member economy to complete the Checklist in 2009. Importantly, Chinese Taipei reported a number of positive results of the process, in addition to the final report, such as greater communication and mutual understanding across government ministries, especially those not explicitly focused on health.

In turn, companies from a broad range of industry sectors with long-term investments in the APEC region understand that healthy populations and workforces are a necessary part of a successful, long term investment strategy. This mutually beneficial relationship is essential for the long term success and prosperity of all involved. As stated in a recent Harvard paper, "There is probably no country in which the private sector is not deeply affected by government regulations and laws, by policies on practice and pharmaceuticals, and increasingly by government funding of private services.

Similarly, almost all governments today rely on the private sector for pharmaceuticals and equipment, and increasingly contract with private (often not-for-profit) organizations for training... and often for direct service delivery in areas where the government does not provide services."<sup>3</sup>

APEC is providing a space where the potential of this collaboration can most be effectively realized as

<sup>3</sup> Marc Mitchell, 'An Overview of Public Private Partnerships in Health,' Harvard School of Public Health, n.d., <http://www.hsph.harvard.edu/ihsq/publications/pdf/PPP-final-MDM.pdf>.



stakeholders collaborate to build capacity and encourage enabling policy environments that have the potential to turn health into an economic asset. The APEC Business Advisory Council (ABAC), a private sector body comprised of senior executives from APEC's 21 member economies, effectively captures this unique synergy in its 2012 Letter to Health Ministers: *"the potential for the private sector to contribute to the development of healthy, productive populations can be enhanced by government steps to encourage innovation, reduce regulatory burdens, and emphasize transparency and compliance while reducing corruption.... the public sector plays an important role in creating a regulatory environment that supports innovation in the life sciences while the private sector contributes by conducting research and development of innovative new products and services. ABAC encourages you and your colleagues to maintain a dialogue with ABAC and other private sector stakeholders to ensure the potential of the private sector is leveraged to the fullest extent."*<sup>4</sup>

## GENERATING RETURNS ON STRATEGIC INVESTMENTS

Smart solutions developed in cooperation with policymakers, industry, and academia can facilitate strategic investments in health systems. These investments can generate strong economic dividends by preventing and mitigating the impact of infections, NCDs, encouraging productive aging, and creating an environment conducive to innovation. Beyond the invaluable benefits of better, longer lives, the economic

return on investments in health can be measured in three immediate ways, according to a 2008 APEC paper developed by experts from Victoria University of Melbourne and Peking University: 1) the proportion of government savings from lower treatment costs, 2) reduced pension payments arising from greater workforce involvement, and 3) increased revenue from higher GDP growth.<sup>5</sup> These returns clearly demonstrate that investing in health care systems should not be perceived as a sunk cost; it is and should be regarded as central to economic development.

However, in an increasingly integrated, complex, and challenging economic environment, such solutions and economic dividends become more attainable when strategic partnerships with industry are combined with a whole-of-government approach. In addition to effective health care policies, finite government budgets need to be strategically leveraged and an open trade and regulatory environment is needed to attract needed skills and development that comes with foreign direct investment. Thus, an integrated approach is required, bringing together expertise in health policy and management, economic and financial analysis, science and technology from government, academia, and the business community.<sup>6</sup> With its institutionalized role for industry participation and institutional capacity to convene senior and working level officials responsible for diverse policy areas such as health, trade, and finance, APEC is uniquely positioned to build on its prior success and further secure prosperity and growth for the region.

4 ABAC 2012 Letter to Health Ministers:[http://aimp.apec.org/Documents/2012/MM/MRT/12\\_mrt\\_009.pdf](http://aimp.apec.org/Documents/2012/MM/MRT/12_mrt_009.pdf)

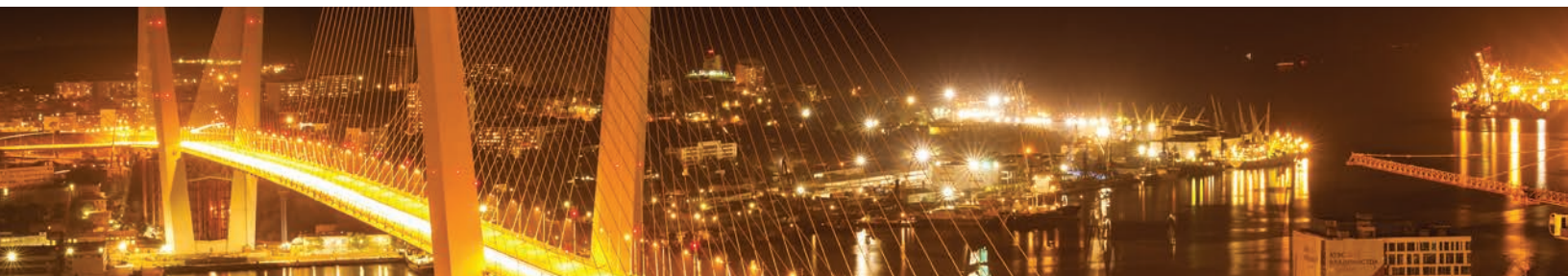
5 Peter Sheehan et al., 'Investing in the Future: An Assessment of the Returns to Investment in Health Innovation.'

6 *Ibid.*, 13.

## INEXTRICABLE LINKS TO HEALTH

<p><b>TRADE MINISTRIES</b></p>	<ul style="list-style-type: none"> <li>• Economic growth improves population health; improved health enhances economic productivity and growth.</li> <li>• Health-related industries remain a bright spot in many economies where jobs and funds for investment are increasingly scarce.</li> <li>• APEC’s health initiatives can also help promote cross-border trade by reducing technical and non-technical barriers to trade.</li> <li>• Intellectual property rights are key for incentivizing health innovation and determining access to needed medicines. IPR protection and enforcement is a key factor for promoting foreign trade and investment, as well as for boosting economic development.</li> </ul>
<p><b>FINANCE MINISTRIES</b></p>	<ul style="list-style-type: none"> <li>• Aging populations and declining birth rates will increase health care costs, shrink the labor force, and drive down GDP growth in APEC economies, impacting the budget position of every government.</li> <li>• Global spending on health care systems and public pensions typically accounts for approximately 40% of government spending.*</li> <li>• Healthy populations support workforce productivity and bolster the tax base.</li> </ul>
<p><b>INDUSTRY</b></p>	<ul style="list-style-type: none"> <li>• A healthy workforce means less absenteeism, turnover, and disability—in other words: good business.</li> <li>• By investing in activities, products, and processes that promote good health, companies develop new markets for their products and services, build community support for their operations, and enhance government and community relationships.</li> <li>• Internationally harmonized guidelines for medical products decrease regulatory burdens on small and large firms seeking new opportunities.</li> </ul>

\* ‘Global Aging 2013: Rising to The Challenge,’ Standard & Poor’s, March 20, 2013, <http://www.standardandpoors.com/ratings/articles/en/us/?articleType=HTML&assetID=1245349076851>.



# LEVERAGING APEC TO CREATE RESULTS: INNOVATIVE PARTNERSHIPS & STRATEGIC INVESTMENTS

## APEC HEALTH LEADERSHIP

### LSIF Co-Chairs

**H.E. Suwit Khunkitti (Chair)**,  
Former Deputy Prime Minister of  
Thailand

**Prof. Peter Sheehan (Academic  
Co-chair)**, Director, Centre for  
Strategic Economic Studies,  
Victoria University, Australia

**Dr. Fikry Isaac (Industry Co-  
chair)**, Vice President, Global  
Health Services and Chief  
Medical Officer, Wellness &  
Prevention, Johnson & Johnson

### HWG Chair

**Dr Svetlana AXELROD (Ms)**,  
Deputy Chief, Unit Department  
of International Cooperation,  
Ministry of Health and Social  
Development of the Russian  
Federation

U.S. Health and Human Services Secretary Kathleen Sebelius addresses health ministers and industry leaders at the first High Level Meeting on Health and the Economy, San Francisco, September 2011.



APEC has long recognized the critical importance of health and the life sciences to economic development. An underlying current in many APEC discussions since the organization's 1989 founding, health became a formal part of APEC's core agenda in Mexico in 2002 with the establishment of the **Life Sciences Innovation Forum (LSIF)**, followed quickly in 2003 by what is now known as the **Health Working Group (HWG)**. Both serve as driving forces for robust activity in APEC.

The LSIF actively discusses policies and promotes a policy environment that fosters the growth of life-sciences innovation and the improvement of public health in the Asia-Pacific region. A tripartite forum, LSIF engages the highest levels of government, industry, and academia. Additionally, APEC created what is now the HWG to address health-related threats to trade and security, focusing mainly on emerging infectious diseases. Today, the HWG agenda complements existing work in other multilateral forums such as the WHO, and focuses on broad range of health policy issues—including pandemic threats, universal health coverage, NCDs, and HIV/AIDS. The HWG is comprised exclusively of government officials, who determine the group's direction.

Both formal APEC bodies have identified specific priorities with concrete results. In keeping with APEC's operational vision, its health policy infrastructure sets ambitious objectives and moves toward them with structured, multi-year initiatives.

## BRINGING LEADERS TOGETHER

### APEC 2011 CEO SUMMIT PROGRAM EXCERPT

Redefining Health: An Economic  
Asset and Competitive Advantage

Discussion Leader:

**Patricia Janiot**, Senior Anchor, CNN en  
Español

Discussion Participants:

**Yasuchika Hasegawa**, CEO, Takeda  
Pharmaceutical Company and  
Chairman, Keizi Doyukai

**Dr. Toby Cosgrove**, CEO, The  
Cleveland Clinic

**William C. Weldon**, Chairman and  
CEO, Johnson & Johnson

High-level exchanges between senior officials, industry leaders, and experts are a key vehicle for bringing the outcomes of APEC's in-depth policy work to the attention of ministers and heads of state. The LSIF and HWG hold an annual joint high-level meeting where they examine issues related to the economic aspects of health. They broke new ground during the 2011 U.S. APEC host year by organizing the first multi-sectoral High Level Meeting on Health and the Economy (HLM): the "Health Systems Innovation Dialogue". The event took place in San Francisco in September 2011 and set a new precedent for Health Ministers and senior industry representatives to formally engage in dialogue on health care policy in the APEC region. The meeting, which engaged six Health Ministers and representatives from 19 economies, facilitated a discussion focused on reducing the economic burden of disease, and resulted in APEC economies agreeing to an ambitious NCD Action Plan that was jointly developed by the LSIF and HWG.

This momentum was reinforced at APEC's CEO Summit, an annual event that engages heads of state and business leaders in policy dialogues. Industry leaders from the health care sector were featured prominently on the agenda and carried forward many key messages from the High Level Meeting. As a result, the profile of APEC's health agenda and the key issues it addresses gained increasing prominence in the region. This was exemplified by Russia's decision to hold a second HLM in St. Petersburg and subsequently incorporate health into its CEO Summit event in Vladivostok during its host year in 2012. Discussions resulted in ministers formally calling for APEC member economies to invest in the health of their populations at all stages of life in order to fully capture the economic returns of healthy and productive populations. Notably, ministers highlighted the high return on investment in maternal and child and health, which was quantified in a preliminary LSIF analysis of economies in the region at up to \$37 for every \$1 spent with benefits extending throughout the life of individuals, especially in terms of NCD prevention and control.<sup>7</sup>

HLM participants also called on APEC Finance Ministers to develop budget processes and measures that factor in good health as a source of economic growth and development. Indonesia is poised to continue to drive this work forward during its host year by organizing a third HLM in Bali in September 2013 that will engage both finance and health ministers in the region in substantive dialogue with industry.

<sup>7</sup> 'Report and Recommendations of the Life Sciences Innovation Forum and Related Meetings,' 24th APEC Ministerial Meeting, Vladivostok, Russia, September 5–6, 2012, [http://mddb.apec.org/Documents/2012/MM/AMM/12\\_amm\\_006.doc](http://mddb.apec.org/Documents/2012/MM/AMM/12_amm_006.doc).

# ISSUE FOCUS: REGULATORY CONVERGENCE OF MEDICAL PRODUCTS

Divergent regulatory systems and regulatory inefficiencies for medical products can present a substantial barrier to industry’s ability to provide safe therapies and medical products to patients in an affordable and timely manner. Regulatory reform and convergence can facilitate trade and promote the growth of a vibrant life sciences industry that meets the needs of consumers by enhancing the efficiency and clarity of the product development and evaluation process.

Industry and academic research institutions depend on predictable and transparent regulatory frameworks to develop innovative products and provide them to patients around the region. The drugs, vaccines,

**“Regulatory reform, including eliminating unjustifiably burdensome and outdated regulations, can boost productivity and promote job creation, while also protecting the environment and public health, safety, and security. In addition, as trade and investment flows become more globalized, greater alignment in regulatory approaches, including to international standards, is necessary to prevent needless barriers to trade from stifling economic growth and employment.”**

Excerpt from APEC Leaders’ Declaration, November 2011, Honolulu



Participants engage in dialogue at the High Level Meeting on Health and the Economy, St. Petersburg, June 2012

devices, and other innovations that support healthy populations and marketplaces require both entrepreneurial-risk (fewer than 10% of medicines tested in human clinical trials actually succeed) and tremendous investment from the bench to the bedside.<sup>8</sup> That investment includes significant time and financial capital, over US \$1 billion on average for pharmaceuticals and \$500 million for devices.<sup>9</sup>

As the medical products sector innovates and produces increasingly diverse and complex products through long, multinational supply chains, economies have implemented a variety of regulatory measures intended to ensure the safety and efficacy of the products that enter their markets. Conforming to regulatory systems that vary by economy requires substantial time and resources for companies. This obstacle is further exacerbated when combined with inefficiencies and lack of regulatory capacity in the implementation of regulatory regimes within economies. Together they create substantial market access barriers both for large multinationals and local firms seeking to expand in the region. Further, small and medium-sized enterprises face a disproportionate burden as they often do not have the capacity to navigate the multitude of regulatory barriers they encounter when venturing into new markets.

To address these challenges, a number of regional stakeholders are promoting regulatory convergence,

a process designed to address regulatory barriers through the establishment, recognition, and application of science based standards consistent with international guidance and best practice and regulatory measures to increase operational efficiency. The information sharing and training that are part of the regulatory coherence process can better equip regulators and agencies to use limited time and resources more efficiently through measures such as eliminating redundant review processes that create unnecessary delays without improving safety and using common data standards to prevent the distribution of counterfeit products and unsafe medicines.

## **HOW IS APEC ADDRESSING THIS CHALLENGE?**

Recognizing the broad economic impact of regulatory convergence, APEC Leaders have committed to improving cooperation among economies in this area. While the potential economic and public health benefits are significant, pursuing regulatory convergence for products in the rapidly evolving and expanding medical device and pharmaceutical sectors can present significant challenges. Economies in the region possess differing levels of regulatory capacity, varying governmental structures and philosophies as well as different public policy objectives. Regulatory convergence initiatives taking place in the LSIF have sought to address this challenge by building bridges between regional and global harmonization efforts already in place and creating structured, goal oriented public private partnerships. In 2008, the LSIF formed two key institutions to develop and advance a

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8 Figure based on the overall success rate for drugs moving through clinical trials to FDA approval from late 2003 to the end of 2010. From: Biotechnology Industry Organization (BIO) Industry Analysis and BioMedTracker (BMT) joint clinical trial success rates study, 2011, <http://www.biotech-now.org/events/2011/02/release-of-biomedtracker-drug-approval-rates-study#>.

9 Tufts CSDD Outlook 2010 Report, Tufts Center for the Study of Drug Development, Tufts University, 2010.

comprehensive, strategic approach to encourage APEC's economies to adopt and implement existing medical product regulatory harmonization guidance developed by existing international harmonization bodies.

The Regulatory Harmonization Steering Committee (RHSC) implements projects and supports the development of policies focused on the adoption and implementation of harmonization guidance and regulatory best practices. The scope of its work covers pharmaceuticals, medical devices and biologics. This enables the sharing of information and best practices across these medical product sectors, leading to better and more streamlined regulatory review practices and the transfer of best practices. The RHSC comprises regulators from all APEC economies (as well as industry representatives and the director of the APEC Harmonization Center.

The work of the RHSC is complemented by the APEC Harmonization Center (AHC), an organization established in Seoul with US \$8 million in funding from the Government of South Korea. The AHC organizes the international workshops, studies, and reports that support the RHSC's objectives and encourage their implementation. In addition, it serves as the RHSC Secretariat and an internal coordinating body, thus ensuring the continuity of APEC's cumulative efforts in regulatory harmonization.

The AHC operates under the authority of LSIF, with direction from RHSC and an international advisory board.

The AHC and RHSC are strong examples of how APEC's inclusive and nonbinding format can be

leveraged to create effective, long-term public-private partnerships that build capacity and help economies achieve ambitious region-wide objectives. Since their founding, APEC has endorsed and funded over a dozen AHC training programs and workshops on various aspects of medical device and pharmaceutical regulations that have brought together hundreds of regulators, experts and industry representatives. The RHSC works synergistically with key regulatory policymaking organizations, such as the International Conference on Harmonization (ICH) for pharmaceuticals; the International Medical Device Regulators Forum (IMDRF) for medical devices, diagnostics, and treatments; and the Asian Harmonization Working Party (AHWP); as well as efforts within ASEAN, WHO, and other organizations. Rather than developing new regulatory guidance, the RHSC reinforces the existing activities of other regulatory bodies by serving as a regional hub for regulatory convergence, connecting efforts across sectors and the diverse socio-cultural contexts of member economies. Importantly, implementation of recommendations occurs on a voluntary basis, enabling an inclusive approach that allows economies with less regulatory capacity to participate and benefit from ongoing work.



## KEY OUTCOME – STRATEGIC FRAMEWORK FOR REGULATORY CONVERGENCE ON MEDICAL PRODUCTS BY 2020

In 2011, APEC Ministers agreed to pursuing regulatory convergence in approval procedures for medical products by 2020 by endorsing “Vision 2020”, the RHSC’s strategic framework to achieve convergence on regulatory approval procedures for medical products (including pharmaceuticals and medical devices) by 2020. The effort calls for detailed roadmaps from economies, which each championing a specific topic (such as cellular therapies, biotherapeutics, or clinical trials).

The RHSC’s roadmap to promote Global Medical Product Quality and Supply Chain Integrity is an excellent example of how this ambitious framework is being applied. Work in this area will ultimately help regulators address the challenge of ensuring that counterfeit or substandard medical products do not enter increasingly long, multinational supply chains by assessing gaps in capacity at the national and regional levels and developing mechanisms to address them, such as training workshops and revisions to existing guidelines. Key components of the roadmap include promoting:

- Sufficient legal, regulatory, enforcement, and laboratory capacity is required at regional, national, and global levels;
- Global regulatory convergence and standards development to drive efficiencies in the global marketplace;
- Systems to authenticate product trace their components to the original manufacturer;
- Information and communication systems and networks to share appropriate information among regulators and law enforcement; and
- Global cooperation and collaboration to leverage resources between member economies and existing medical product quality and supply chain integrity initiatives, regulatory authorities, knowledge, and expertise.

In 2013 APEC Ministers declared their support for the establishment of a Center of Excellence for regulatory sciences cooperation under the RHSC Multi-Regional Clinical Trials (MRCT) roadmap, a groundbreaking institution that will be instrumental in addressing capacity gaps by enhancing the understanding of the requirements for acceptance of MRCT results for review by regulatory authorities, facilitating training in internationally recognized technical guidance and promoting science based review and evaluation of MRCTs.

## PRIORITY WORK AREAS WITHIN THE STRATEGIC FRAMEWORK

- Multi-regional Clinical Trials (Led by Japan)
- Global Medical Product Quality and Supply chain Integrity (Led by U.S.)
- Good Review Practices and Combination Products (Led by Chinese Taipei)
- Biotech Products and Pharmacovigilance (Led by Korea)
- Good Clinical Practice Inspection (Led by Thailand)
- Cellular Therapies (Led by Singapore)



# ISSUE FOCUS: NON-COMMUNICABLE DISEASES (NCDs)

**NCDs, including cancer, cardiovascular disease, and diabetes, impact the heart and soul of economic development. They represent a majority of deaths and medical costs in a typical APEC economy. Beyond the burden to individuals and caregivers, the economic toll of lower productivity, disability, and absenteeism in the workplace is severe, making industry a natural stakeholder in the discussion.**<sup>10</sup>

For the private sector, NCDs lead to increased employee health insurance and disability expenditures, decreased workplace productivity and less affluent and unhealthy consumers, all of which create a drag on economic output. Indeed, the World Economic Forum's annual Executive Opinion Survey shows that "about half of all business leaders surveyed worry that at least one NCD will hurt their company's bottom line in the next five years, with similarly high levels of concern" across all economies—especially in those where the quality of, or access to, healthcare is limited.<sup>11</sup>

On a broader scale, NCDs account for 63% of

## NCD BURDEN IN APEC ECONOMIES

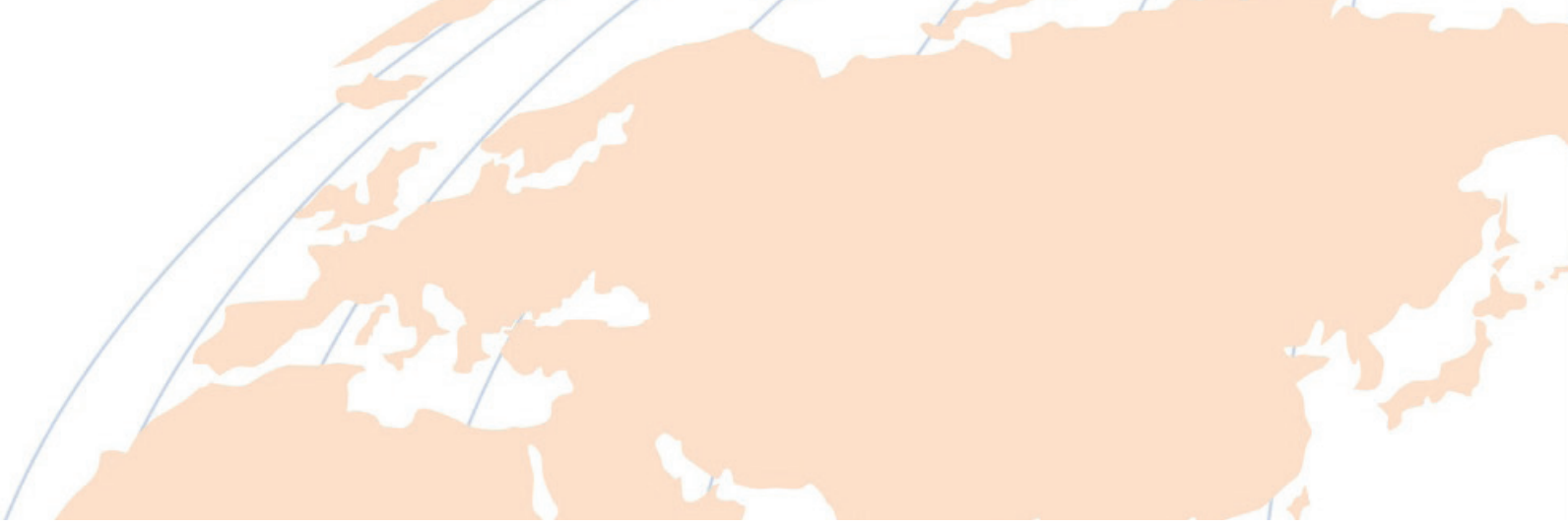
- Cardiovascular disease accounts for about one third of all deaths in Asia, with mortality, on average, 70% higher than in OECD countries.
- Cancer caused an estimated 13% of total deaths in Asian economies in 2008—almost half of all worldwide cancer deaths.
- In 2012, diagnosed diabetes cost the U.S. approximately US \$176 billion in direct medical costs.
- Asian economies spent around US \$77 billion on diabetes care in 2011, with Japan, at US\$35 billion, spending most.

Sources: 'Health At A Glance: Asia/Pacific 2012,' OECD/World Health Organization (2012), OECD Publishing, on OECD website, <http://dx.doi.org/10.1787/9789264183902-en>.

<sup>10</sup> 'Addressing the Chronic Disease Challenge in the APEC Region: An Innovative Approach to Collaborative Action,' Agenda item 1a, 23rd APEC Ministerial Meeting, Hawaii, USA, November 11, 2011, [http://mddb.apec.org/Documents/2011/MM/AMM/11\\_amm\\_004att2.doc](http://mddb.apec.org/Documents/2011/MM/AMM/11_amm_004att2.doc).

<sup>11</sup> D.E. Bloom, E.T. Cafiero, E. Jané-Llopis, S. Abrahams-Gessel, L.R. Bloom, S. Fathima, A.B. Feigl, T. Gaziano, M. Mowafi, A. Pandya, K. Prettnner, L. Rosenberg, B. Seligman, A.Z. Stein, & C. Weinstein, 'The Global Economic Burden of Noncommunicable Diseases,' 2011, Geneva: World Economic Forum.





deaths worldwide, and cases of cardiovascular disease, cancer, and diabetes will increase exponentially in coming decades as populations age. In addition to burdening elderly populations, NCDs are also affecting populations at younger ages, particularly in low- and middle-income countries, where a majority of deaths from NCDs, and about 80% of all disability, occur before the age of 60. This is largely a result of urbanization, persisting poverty, lack of access to health care, and the “globalization” of behavioral risk factors such as high-sugar diet and lack of exercise.<sup>12</sup> As a result, the economies that are least able to afford the consequences of this rising burden will see longer periods of ill-health, premature death, and greater loss of the productivity that is critical for economic development.

A reduced ratio of workers to dependents with poor health across the APEC region as a result of the rising NCD burden increases the odds of a future economic slowdown. The WHO warns that the existing substantial burden will evolve into “a staggering one” over the next 20 years, posing a fundamental challenge

to social and economic development of member economies, especially in the context of a continued burden of infectious diseases.<sup>13</sup> Indeed, according to a 2012 study conducted by the LSIF and WHO, NCDs will lead to a global loss of US \$47 trillion over the next two decades—the equivalent of an annual 4% reduction in GDP.<sup>14</sup>

Taking action on NCDs has become an increasingly critical business imperative, and also presents an opportunity to innovate around creative, responsible solutions and effective strategic partnerships. NCD challenges create a growing need for innovation around affordable and accessible diagnostics and treatments, and businesses throughout the APEC region are deeply engaged in finding solutions, particularly through public-private partnerships.

Fortunately, prevention can yield meaningful health and economic results by reducing the burden of care and enabling individuals to be more socially and economically engaged. The WHO has identified cost-effective prevention approaches could reduce the NCD burden by more than 50%, while costing a small

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12 Montserrat Meiro-Lorenzo, Tonya L. Villafana, and Margaret N. Harrit, “Effective Responses to Noncommunicable Diseases: Embracing Action beyond the Health Sector,” World Bank, Health, Nutrition, and Population Discussion Paper, September 2011.

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13 Ibid.

14 Ibid.



fraction of current health spending. Importantly, the benefit of preventive measures relative to their cost is immense. For example, if China reduced cardiovascular disease mortality by just 1% each year over 30 years, the economy could generate an equivalent of about 68% of China's real GDP in 2010, or more than US \$10.7 trillion.<sup>15</sup> Businesses can also benefit from prevention, as demonstrated by an analysis that showed a return of US \$3.27 for every \$1 spent on employee wellness programs in large multinationals.<sup>16</sup>

## HOW IS APEC ADDRESSING THIS CHALLENGE?

During its U.S. host year in 2011, APEC, together with the WHO and the UN, contributed to a major arc of related international events on NCDs. These activities articulated the scope of the problem and its widespread

and diverse impact on economic and human health, as well as kept these issues on the international agenda in concrete ways.

Officials at the first APEC HLM on Health in September 2011 used the meeting as a platform to highlight APEC's success in jointly combating infectious diseases, such as SARS and the H1N1 flu virus, and calling for similar cooperation on the now greater threat of NCDs.<sup>17</sup> A critical outcome was a groundbreaking APEC NCD Action Plan, calling on economies to define health as an economic opportunity and address the challenge of rising NCDs by engaging health stakeholders and diverse government agencies in the development of health policy, strengthen health systems by building new public private partnerships to leverage innovations, sharing best practices between economies and measuring outcomes. APEC governments were asked to submit an annual report on their progress in implementing the action plan. To date a significant number of APEC economies have submitted reports, providing guidance to officials still engaged in the implementation process.

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15 'Toward a Healthy and Harmonious Life in China: Stemming the Rising Tide of Non-Communicable Diseases,' World Bank, July 26, 2011, <http://www.worldbank.org/en/news/feature/2011/07/26/toward-health-harmonious-life-china-stemming-rising-tide-of-non-communicable-diseases>.

16 Katherine Baicker, David Cutler, and Zirui Song, 'Workplace Wellness Programs Can Generate Savings,' *Health Affairs* 29, vol. 2 (February 2010): 304–11.

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17 Sebelius, speech for APEC 2011 Meeting.

# ISSUE FOCUS: HEALTHCARE-ASSOCIATED INFECTIONS (HAIs)

**Patients acquire healthcare-associated infections (HAIs), also known as nosocomial infections, while receiving treatment for another condition in some type of health care facility. Health care costs of patients with HAIs are six times that of non-infected patients. The benefits of HAI prevention in the United States are estimated to range from \$5.7 to \$31.5 billion<sup>18</sup> and are likely greater in less developed APEC economies where the burden is higher. Developing economies experience incident levels at least twice as high as in developed economies, with one in four patients admitted to hospitals acquiring HAIs.**

Examples of HAIs include pneumonia, bloodstream infections, and urinary tract infections. Patients who are hospitalized, especially those in critical care, are constantly at risk of developing these infections, which require specialized treatment and lead to longer hospital stays. Other consequences of HAIs include long-term disability, preventable deaths, and increased antimicrobial resistance. The WHO estimates that HAIs affect hundreds of millions of patients annually.

In 2002, one in every 20 hospitalized patients in the U.S. developed an HAI, making HAIs one of the leading causes of death and illness in the U.S., and

18 R. Douglas Scott II, "The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention," U.S. Centers for Disease Control and Prevention, March 2009, [www.cdc.gov/HAI/pdfs/hai/Scott\\_CostPaper.pdf](http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf).



costing up to \$33 billion dollars, according to the Department of Health and Human Services.<sup>19</sup> Similarly, in 2009, HAIs cost the Australian health care system more than 850,000 lost bed days (a day during which a person is confined to a bed and in which the patient stays overnight in a hospital). In other words, beds are unavailable for other conditions because they are being occupied by patients with HAIs.<sup>20</sup> According to an expert at the Queensland University of Technology, "If rates were reduced by just 1%, then 150,158 bed days (would be released for alternative uses [in Australia], allowing an estimated 38,500 additional admissions annually."<sup>21</sup> In economies with even larger hospital bed shortages, lost bed days have a severe impact. In Malaysia, HAIs were the reason for 13.9% of the total

19 Emily Walker, "Hospital Acquired Infections Costly, Preventable," MedPage Today, August 24, 2011, <http://www.medpagetoday.com/HospitalBasedMedicine/InfectionControl/28185>.

20 "Hospital Infections in Australia Cost \$1 Billion in Lost Bed Days," Science Daily, September 2, 2009, <http://www.sciencedaily.com/releases/2009/09/090902112107.htm>.

21 Ibid.

hospital admissions in 2010.<sup>22</sup>

For hospitals, HAIs “erode the bottom line.” Hospital executives tend to be generally aware of the impact of HAIs on patients, but often underestimate the degree to which HAIs impact hospital costs and operating margins. In systems where reimbursement for these preventable infections is low, losses are even greater.<sup>23</sup>

Fortunately, many HAIs can be prevented when public policy requires and incentivizes health care facilities to implement comprehensive infection prevention and control practices.<sup>24</sup> For example, the U.S. Centers for Medicare & Medicaid Services (CMS) has stopped reimbursing hospitals for treating conditions, infections, or illnesses that were acquired

in the hospital, and for any readmissions associated with treating those HAIs. As a result, HAI prevention becomes not only critical to patient survival but also to health care facilities’ bottom lines. CMS Administrator Donald Berwick stated that these steps “encourage health professionals and hospitals to reduce preventable infections and eliminate serious medical errors.... As we reduce the frequency of these conditions, we will improve care for patients and bring down costs at the same time.”<sup>25</sup>

Surveillance is another key HAI management and prevention tool as long as it is implemented along with multidimensional infection control approaches that include education and training for personnel, infection control monitoring, and performance feedback. China, with the largest, real-time disease surveillance system in the world, established its Guidelines for Surveillance and Prevention of Nosocomial Infections in 1994, providing early HAI prevention and control policy leadership. However, similar to challenges faced throughout the APEC

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22 “Malaysia Moves to Eradicate Hospital-Acquired Infections,” eGov Innovation, November 4, 2011, <http://enterpriseinnovation.net/article/malaysia-moves-eradicate-hospital-acquired-infections>.

23 Denise Murphy and Joseph Whiting, “Dispelling the Myths: The True Cost of Healthcare-Associated Infections,” Association for Professionals in Infection Control and Epidemiology, Briefing Paper, February 2007.

24 American Chamber of Commerce in Japan, Investing in Health as a Competitive Advantage: Proposals to Reduce the Economic Burden of Disease by Promoting Prevention and Early Detection, November 2011, [http://www.accj.or.jp/en/about/committees/committee-materials/cat\\_view/13-materials/56-healthcare](http://www.accj.or.jp/en/about/committees/committee-materials/cat_view/13-materials/56-healthcare).

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25 Emily Walker, “Medicaid to Quit Paying for Preventable Events,” MedPage Today, June 1, 2011, <http://www.medpagetoday.com/PublicHealthPolicy/Medicaid/26808>.

**“HAIs add to the functional disability and emotional stress of the patient and may in some cases, lead to disabling conditions that reduce the quality of life. The economic costs of this menace are considerable. The increased length of stay for infected patients is the greatest contributor to its costs. Prolonged stay not only increases direct costs to patients and payers but also indirect costs due to lost work.”**

Enrique Ona, Secretary of Health of the Philippines at the 1st APEC High-Level Workshop on Reducing the Economic Burden of Healthcare-Associated Infections, July, 2012, Manila

region, the economy's size and diverse level of advancement throughout its health system have made implementation of these guidelines challenging.

Industry is a critical knowledge partner for hospitals and policymakers as they establish and implement effective policies that fight HAIs. A cross-sector approach is critical: industry helps alleviate capacity gaps and is strongly incentivized to provide doctor and nurse training and education for the safe administration of medical products.

But before APEC can implement better prevention and control strategies, the problem must be more accurately measured. While well-documented in the West, there is a dearth of data in many APEC economies on the scale and impact of the problem. The International Nosocomial Infection Control Consortium (INICC)<sup>26</sup> concluded that, compared to the developed world, HAIs (including device-associated infections in particular) in intensive care units in countries with limited resources pose an even higher risk to patient safety.<sup>27</sup> The study included hospitals in APEC member economies, namely Thailand, Vietnam, China, Philippines, Mexico, and Peru. INICC's surveillance data show that while device utilization in ICUs in developing countries is similar to that in the United States, rates of device-associated infections were markedly higher in limited resource countries.<sup>28</sup>

26 The INICC is an international scientific organization with the mission to reduce HAIs via a global network. See [www.inicc.org](http://www.inicc.org) for more information.

27 Victor D. Rosenthal et al., "International Nosocomial Infection Control Consortium (INICC) Report, Data Summary for 2003–2008, Issued June 2009," *American Journal of Infection Control* 38 (2010): 95–106.

28 Marilyn Cruickshank and John Ferguson, eds., *Reducing Harm to Patients from Health Care Associated Infection: The Role of Surveillance* (Sydney: Australian Commission on Safety and Quality in Health Care, 2008), 3.



## EFFECTIVE POLICIES FOR HAI PREVENTION AND CONTROL CASE STUDY: JAPAN

Japan's step-by-step, country-wide actions to enhance HAI prevention and control include both organizational changes in hospitals and government incentives, creating enhanced infection prevention and control at health care facilities, and strengthening the pandemic readiness of frontline health care facilities.

In 2007, Japanese medical law obligated all health care institutions to implement operational safety measures against HAIs. Core components include hospital infection prevention guidelines, implementing employee infection prevention training, and disease reporting.

In 2011, the Ministry of Health, Labour and Welfare issued an official ordinance containing guidance on establishing infection control teams within health care facilities, criteria for disease reporting, and collaboration between institutions for complex cases. The ordinance's 2012 medical fee revision raised the subject of hospital fees for infection control efforts. Issues still under discussion include consequences for noncompliance.

Recent government statements further support stronger mandated infection control.



In developing economies, HAI rates are higher, albeit still inadequately measured, because ICU equipment tends to be less advanced than in developed countries, medical resources are relatively insufficient, wards tend to be crowded, nurse-patient ratios are low, and there is often low compliance with preventive measures.

## **HOW IS APEC ADDRESSING THIS CHALLENGE?**

APEC's HAI initiative aims to build infection prevention and control capacity in all APEC economies regardless of available resource levels by leveraging collaborative partnerships between government, professional societies, and industry as a knowledge partner to facilitate effective best practices and information sharing region-wide.

HAIs first appeared on the APEC agenda in September 2010, resulting in an official economic Ministers Statement acknowledging HAIs as both a health and economic problem, and thus a key priority for APEC. The LSIF then established an HAI work

program and public-private partnerships to measure and address HAIs in the region.

The first APEC High Level Workshop on Reducing the Economic Burden of Healthcare-Associated Infections, which took place in Manila in July 2012, resulted in representatives from academic institutions, hospitals, health care associations, patient organizations, and the medical technology industry agreeing on a set of three initial steps member economies should undertake to begin reducing the huge economic burden of HAIs: (1) invest in infection prevention and control policies and programs; (2) enhance data collection and surveillance; and (3) encourage partnerships and collaborations to help tackle the HAI burden. The meeting concluded with a set of recommendations calling on Ministers to recognize the economic and public health burden of HAIs and encouraging APEC economies to commit to working with stakeholders to reduce the incidence of infections in health care settings by establishing surveillance systems, baseline measurements, and targeted reduction goals at the economy and local levels by 2015

The second High-Level Workshop on HAIs in Medan in summer of 2013 will focus on the economic cost burden of HAIs and principles of Ethical public-private partnerships for best practice sharing region-wide.

**“We welcome work to address the economic and public health burden of healthcare associated infections. We encourage officials to work with stakeholders to reduce the incidence of infections in healthcare settings.”**

APEC Ministerial Meeting, September 2012, Vladivostok

# ISSUE FOCUS:

## ETHICAL BUSINESS PRACTICES IN THE MEDICAL DEVICE AND BIOPHARMACEUTICAL SECTORS

**Ethical business practices facilitate open and transparent business environments free from the high costs of corruption, enhancing industry's ability (especially resource-constrained SMEs) to participate in global markets, engage in appropriate collaborations with health care professionals to develop advanced medical technologies and medicines, and focus scarce resources on critical investments in R&D and innovation. Empirical evidence shows that economy-wide corruption encourages inflation, decreases GDP, reduces foreign investment, and undermines health systems.<sup>29</sup>**

Ethical business practices help ensure that medical decisions are made in the best interests of patient care and the practice of medicine. These practices include actions, attitudes, and principles that are considered professionally and morally responsible. Examples of unethical practices include bribery, falsification of evidence, and mismanagement of conflicts of interests. Economies with a lack of enforced medical product legislation and regulation, are among the most severely affected by unethical business practices. Unfortunately, numerous APEC economies still fall in this category. As the nearly \$530 billion global pharmaceutical and medical device industries expand and competition

heightens, the potential for fraudulent activity, corrupt practices, and compliance issues will increase as well.<sup>30</sup> The consequences are severe, ranging from costly health system waste to life-threatening counterfeit and substandard products.

Costs created by corruption in the health care industry have been estimated at up to US \$23 billion in individual developed economies.<sup>31</sup> The health consequences are equally extreme: in addition creating barriers between patients and needed medicines and diagnostics, economies with more corruption have higher child mortality rates. These unethical practices carry negative, destabilizing consequences for government by eroding public confidence in their health systems and governments. Industry also suffers; corrupt practices result in untold expense, waste, and reputational losses which directly impacts companies' bottom line.

State and federal governments pay hundreds of billions of dollars each year for pharmaceuticals and

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30 Brian J. Mich and Ryan Starkes, "The Right Prescription for the Foreign Corrupt Practices Act in the Pharmaceutical Industry," *Pharmaceutical Compliance Monitor*, January 1, 2013, <http://www.pharmacompliancemonitor.com/the-right-prescription-for-the-foreign-corrupt-practices-act-in-the-pharmaceutical-industry/3789/>; and "Medical Devices Industry: Market Research Reports, Statistics and Analysis," *ReportLinker*, <http://www.reportlinker.com/ci02249/Medical-Devices.html>.

31 "Medicines: corruption and pharmaceuticals," *World Health Organization, Fact Sheet 335*, December 2009, <http://www.who.int/mediacentre/factsheets/fs335/en/>.

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29 Philip M. Nichols, remarks at "APEC Business Ethics for SME" workshop, Gifu, Japan, September 27, 2010.



**“Acknowledging that corruption fuels illicit trade and insecurity and is a tremendous barrier to economic growth, the safety of citizens, and to the strengthening of economic and investment cooperation among APEC economies, we endorse commitments on fighting corruption and ensuring transparency...We recognize the important role of business and public-private partnerships in promoting the elaboration of codes of conduct in the private sector and measures to fight corruption, especially measures that support the promotion of ethical business practices in interactions between government, business and other stakeholders.”**

2012 Leaders' Declaration (Vladivostok Declaration)

medical devices, relying on companies and individuals to act in an ethical manner. Industry does the same, investing billions, decades, and reputations on their R&D, recognizing that ethical relationships with health care professionals are essential to collaborations that lead to advanced medical technologies and medicines. Patients invest their greatest possessions: their lives. International and national guidelines do exist, but in sporadic, fragmented, form. In an increasingly interconnected world, harmonized regional solutions with buy-in at the highest levels are needed.

## **WHAT IS APEC DOING TO ADDRESS THIS CHALLENGE?**

In 2011 APEC Ministers endorsed voluntary codes of business ethics for the medical devices and biopharmaceutical sectors. These are known as “The Kuala Lumpur Principles for Medical Device Sector

Codes of Business Ethics”<sup>32</sup> and “The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector.”<sup>33</sup> These were drafted by expert working groups consisting of government, industry, and civil society. In 2012 APEC Leaders recognized this work and the importance of a public-private partnership approach to addressing the issue. In 2012 workshops were held to help associations throughout the APEC region to write or update codes of ethics aligned with the APEC principles. In 2013 Malaysia will host a five-date train-the-trainer compliance workshop and Indonesia will host a workshop aimed at generating complementary activities among anti-corruption and health officials, as well as hospital and physician groups.

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32 “The Kuala Lumpur Principles - Medical Device Sector Codes of Ethics,” Agenda item 3, APEC 18th Small and Medium Enterprises Ministerial Meeting, Big Sky, USA, May 21, 2011, [http://mddb.apec.org/Documents/2011/MM/SMEMM/11\\_smemm\\_009.pdf](http://mddb.apec.org/Documents/2011/MM/SMEMM/11_smemm_009.pdf).

33 “The Mexico City Principles,” Agenda item 4.4, APEC Life Sciences Innovation Forum Planning, Group Meeting, Moscow, Russia, February 2, 2012, [http://mddb.apec.org/Documents/2012/LSIF/LSIF1/12\\_Isif1\\_017.pdf](http://mddb.apec.org/Documents/2012/LSIF/LSIF1/12_Isif1_017.pdf).

# ISSUE FOCUS: HARNESSING TECHNOLOGY FOR AN AGING SOCIETY

**The need and market for independent living solutions in APEC member economies is significant given the longevity of their populations. Information technology is the game changer of the modern age. It is playing a fast-growing role in making health care more cost-effective, accessible, and safe for individuals, economies, and industry while helping health systems deal with the consequences of rapidly aging populations.**<sup>34</sup>

Health Information Technology (HIT) is an umbrella term that describes the comprehensive management of health information across computerized systems and its secure exchange between consumers, providers, government and quality assurance entities, and insurers. Given the ubiquity of the internet and the leadership of APEC economies in digital communication, HIT presents enormous opportunities for the region through telehealth, electronic health records, health kiosks, and monitoring technology that will enable seniors to age with more independence at home. It also helps economies measure the impact of their investments in health by serving as a tool to track patient development and health outcomes.

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<sup>34</sup> Kate Vernon, "Ageing: Impact on Companies in Asia," Diversity and Inclusion in Asia Network, Community Business, March 2010, <http://www.communitybusiness.org/images/cb/publications/2010/Ageing.pdf>.

Extreme demographic shifts and rising health care costs create opportunities, as well as concern. Governments are investing heavily in R&D to serve the growing elderly demographic and to deliver health care more quickly and accurately than before. If more cost-effective, efficient health care is the end, then IT is one of the most critical means – for innovation and for generating cost-savings. In recognition of the value of investments in this area, the U.S. included US \$20 billion for HIT measures as part of its economic stimulus expenditures.<sup>35</sup>

If properly implemented, these advances will help reduce pressure on health systems and caregivers in addition to improving seniors quality of life—all while providing crucial information to physicians to facilitate the early detection and prevention of costly medical conditions. Indeed, a new industry exists that is growing rapidly in APEC's digitally-advanced economies, one that is providing cost-effective solutions to new pressures on health systems and creating compelling investment opportunities with the potential for very significant financial return.

With one of the world's fastest-aging populations, Chinese Taipei faces significant challenges with health

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<sup>35</sup> Chanley Howell, "Stimulus Package Contains \$19 Billion for Health Care Technology Spending and Adoption of Electronic Health Records," WTN News, February 19, 2009, <http://wtnews.com/articles/5523/>.



Robert Hormats, U.S. Under Secretary of State for Economic, Energy and Agricultural Affairs, leads a discussion at the APEC Dialogue on Aging, Health, and Innovation, San Francisco, 2011

care costs and services and has long recognized IT as a critical tool in addressing them. In 2008, the City of Taipei launched a plan that implements telecare services to keep the elderly and chronically ill out of large, costly hospitals by monitoring them in their communities and homes. The plan, “Citizen Telecare Service System” (CTCS), now in its sixth year, created a system that provides five different health care models—homecare, community care, nursing home care, workplace care, and self-managed care for citizens—in all 12 districts of Taipei City. According to the Global Coalition on Aging, impact analyses between 2009 and 2011 showed a significant reduction in high systolic blood pressure among the program’s participants. Importantly, the users were highly satisfied with the system. As Chinese Taipei and the rest of the world work to improve health care delivery while reducing costs, the publicly supported CTCS offers valuable lessons. In the U.S.,

pilot telehomecare programs resulted in a dramatic drop in the rate of hospitalizations, ER visits and total medical costs in their communities.<sup>36</sup>

Another example of how HIT has become integral for economic sustainability is China’s 12th-five-year-plan, which includes a goal to have 90% of seniors remain independent in their homes in coming years; IT will be an essential tool for achieving this goal. This economy has prioritized investment in IT as a key enabler and cost-saver in health. In addition to its cutting-edge infectious and chronic disease surveillance system, China is one of the world’s first economies to start building an integrated summary electronic health record for all its citizens – both urban and rural. A key element of China’s \$124 billion health care sector

<sup>36</sup>Michelle Mazzacco, “Study Confirms Benefits of Home Telehealth,” *Educator* 1, vol.1 (September 2010): 11–12. Volume 1, Edition 1 (Se2).

“Continued investment and innovation in technologies that enable independent living and in-home care solutions will be crucial for APEC economies, given the region’s population aging trends and its cultural legacy of respect and honor for seniors.”

Eric Dishman, Intel Fellow and General Manager, Health & Life Sciences Group

stimulus package is digital hospitalization, electronic medical records, and next-generation information networks. The goal is to dramatically improve health care service quality and to enable virtual health care services that can overcome service disparities between rich and poor areas.

A 2005 RAND study showed that rapid adoption of health IT could save the United States more than US \$81 billion in health care spending annually. To achieve these cost-savings, analysts have flagged the necessity of interoperability (the ability for IT systems to talk to each other and exchange information). Almost all APEC economies have made significant investments in electronic health records, in telehealth, and in clinical systems support, but for those investments to ensure their potential return, doctors, clinics, and hospitals must be able to exchange data with one another. That data ultimately has to be able to be acquired and shared in real-time.

The technical capability to improve health and health care, in spite of the APEC region's triple burden threat, exists; the challenges now are logistical and political. Electronic health records, telehealth, and other forms of HIT, can provide many benefits for providers and their patients, but the benefits depend on how, and the environment in which, they are used. Their success requires proper deployment and training of personnel, patient education and support, and care coordination with all stake holders. Interoperability is also critical to comprehensive solutions: the ability to easily exchange data at the local, regional, and national levels is an essential element in any effort to improve health outcomes. In recognition, China and the U.S.

recently signed memoranda of understanding to develop standards for sharing electronic health records and best practices. Finally, privacy and security safeguards are essential both to mitigate risk and incentivize engagement.

## **HOW IS APEC LEVERAGING THIS OPPORTUNITY?**

During the US APEC host year, the HWG held two policy dialogues in 2011 on Aging, Health, and Innovation in Washington, DC, and San Francisco. The goal of both discussions was to develop strategies for a life-course approach to healthy and active aging, promote innovation around aging populations, and share best practices that allow economies to thrive in the face of 21st Century demographic realities. In a region with growing longevity and a legacy of honoring seniors, experts noted that the very concepts of “community” and “health care” would be shifting. Discussions emphasized technology as a key connecting force, a tool for generating cost savings, and a unique market opportunity, particularly in the areas of social engagement and support for seniors, the prevention and early detection of illness and injury, and at-home chronic disease monitoring and management.

Numerous events built on these dialogues in 2012, including a third, related policy dialogue in St. Petersburg entitled Using Health IT to Connect and Strengthen the Health Care System. The dialogue drew attention to the cost-savings HIT can generate, as well as its potential to improve health care safety and quality. Telehealth was measured to be 150 times less expensive

in the host economy, Russia, than a trip to the doctor's office.<sup>37</sup> That year, APEC Telecommunications Ministers emphasized the need for economies to share experiences and best practices to enable more effective use of information and communications technology to improve regional economic cooperation in health care and address economic and social issues.

In addition, APEC and the OECD organized a joint workshop at Waseda University in Tokyo that explored how to transform the global aging challenge

into new sources of growth in such areas as health and nursing care, education, transportation, and community development. The workshop concluded that countries must innovate to mitigate aging's impact, including accelerating innovation and better leveraging new and existing information technologies.

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<sup>37</sup>Alexey Kholin, Oleg Kazankov, and Valery Stolyar, "Telemedicine as a Tool to Improve Quality, Safety, and Costs of Health Care: Russian Experience" (conference presentation, APEC Policy Dialogue on Using Health IT to Connect and Strengthen the Health Care System, St. Petersburg, Russia, June 26, 2013).



# CONCLUSION

**B**oth industry and governments have vested interests in strengthening health and healthcare systems in the Asia Pacific region. Industry's unique capacity to help address the region's significant health challenges can be most effectively leveraged through substantive public-private partnerships and the creation of a policy environment that reduces regulatory burdens and promotes open investment and competition. These trends further enable business and government to make strategic, high impact investments in healthcare systems that can improve quality of life as well as generate substantial economic returns in the form of lower healthcare costs, productive workforces, and a more competitive and innovative life sciences industry.

APEC has proven itself as an effective and inclusive forum where industry and government officials can convene and collaborate around evolving challenges from a multisectoral perspective with the aim of developing solutions that facilitate the exchange and implementation of best practices, capacity building, and promotion of an efficient regulatory environment. In addition, it has enabled senior representatives from industry and governments to broadly raise awareness of the healthcare challenges facing the region and urge action to address them.

To date, APEC's substantial efforts, particularly through the LSIF, RHSC, and AHC have generated

significant results and partnerships that hold great promise. Continued multisectoral engagement from industry and cross-ministry participation from governments will be essential to ensuring that the important work taking place in this forum continues to expand in scope and impact.

## **Recommended Actions for APEC Stakeholders:**

- **Demonstrate that Health is an Economic Asset:** Further efforts to raise awareness of existing evidence and metrics that demonstrate the returns on healthcare and health policy investment will broaden the understanding that health is an economic asset rather than a sunk cost.
- **Expand Private Sector Engagement:** Ongoing work by APEC's health stakeholders to improve regulatory environments, promote ethical business conduct, secure supply chains, and promote healthy, productive workforces impacts the broader business community. Continued engagement from private sector bodies such as the APEC Business Advisory Council can help leverage APEC's work and further promote successful outcomes.
- **Leverage New and Existing APEC Tools:** APEC has generated useful tools designed to promote broad progress on key issues, such as the APEC NCD Action Plan, Enablers of



Investment Checklist and voluntary codes of ethics such as the Mexico City Principles and Kuala Lumpur Principles. APEC economies should continue to promote implementation of these tools and report on lessons learned.

- **Enable Economies to Leverage Health IT :** Health-IT solutions have the capacity to increase efficiency and promote empowered, active aging. APEC is well positioned to undertake further work to enable economies to address barriers to the adoption of health IT, such as divergent standards, privacy concerns, and care coordination.

- **Facilitate High Level, Multisectoral Dialogues:** APEC has served as a convening forum for ministers responsible for diverse areas of policy such as trade, finance, SMEs, and health. Future host economies should continue to facilitate high level discussions on health through events, such as the High Level Meeting on Health and the Economy and APEC CEO Summit, which engage a diverse group of senior policymakers and industry representatives. Future high level exchanges will be essential to building awareness and momentum for existing work as well as the development of new, high impact initiatives.

# RESOURCES

## APEC Health Stakeholders

- LSIF: <http://www.apec.org/Groups/Committee-on-Trade-and-Investment/Life-Sciences-Innovation-Forum.aspx>
  - RHSC: <http://www.apec-rhsc.org/index.do>
  - AHC: <http://www.apec-ahc.org/index.do>
- HWG: <http://www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Working-Groups/Health.aspx>

## KEY APEC Documents

- APEC LSIF Enablers of Investment Checklist: [http://mddb.apec.org/Documents/2012/LSIF/LSIF3/12\\_lsif\\_008.pdf](http://mddb.apec.org/Documents/2012/LSIF/LSIF3/12_lsif_008.pdf)
- APEC Framework on the Investment Case for Health  
Investing in the Future: An Assessment of the Returns on Investment to Health Innovation: [http://www.cfses.com/documents/2008\\_CSES\\_LSIF\\_VI\\_APEC\\_Investing\\_in\\_the\\_Future.pdf](http://www.cfses.com/documents/2008_CSES_LSIF_VI_APEC_Investing_in_the_Future.pdf)

## Regulatory Harmonization

- RHSC: <http://www.apec-rhsc.org/index.do>
- AHC: <http://www.apec-ahc.org/index.do>
  - AHC Background: [http://www.apec-ahc.org/files/AHC\\_leaflet.pdf](http://www.apec-ahc.org/files/AHC_leaflet.pdf)
- IMDRF: <http://www.imdrf.org/>
- AHWP: <http://www.ahwp.info/>
- Mexico City Principles For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector: [http://phrma.org/sites/default/files/pdf/apec-the\\_mexico\\_city\\_principles-final.pdf](http://phrma.org/sites/default/files/pdf/apec-the_mexico_city_principles-final.pdf) [Is it okay to link to the phrma website here?]
- Kuala Lumpur Principles: Medical Device Sector Code of Ethics: <http://www.apec.org/en/Press/News-Releases/2011/~-/media/Files/Press/NewsRelease/2011/The%20Kuala%20Lumpur%20Principles.ashx>
- Vision 2020: A Strategic Framework - Regulatory Convergence for Medical Products by 2020: [http://aimp.apec.org/Documents/2011/MM/AMM/11\\_amm\\_004att1.pdf](http://aimp.apec.org/Documents/2011/MM/AMM/11_amm_004att1.pdf)

## Non-Communicable Diseases

- WHO-LSIF 2012 report: Link [www.cfses.com/documents/2012-CSES-&-WHO-Investing-in-MNCH.pdf](http://www.cfses.com/documents/2012-CSES-&-WHO-Investing-in-MNCH.pdf)
- NCD Action Plan: Link [http://mddb.apec.org/Documents/2012/LSIF/LSIF3/12\\_lsif\\_008.pdf](http://mddb.apec.org/Documents/2012/LSIF/LSIF3/12_lsif_008.pdf)

## Healthcare-Associated Infections

- APEC 2012 HAI Policy Recommendations: [http://mddb.apec.org/Documents/2012/MM/AMM/12\\_amm\\_008.doc](http://mddb.apec.org/Documents/2012/MM/AMM/12_amm_008.doc)

## APEC Business Advisory Council (ABAC)

- ABAC 2012 Letter to Health Ministers: [http://aimp.apec.org/Documents/2012/MM/MRT/12\\_mrt\\_009.pdf](http://aimp.apec.org/Documents/2012/MM/MRT/12_mrt_009.pdf)











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