

# APEC Health Initiatives

John Steele

Director, International Government Affairs

Eli Lilly and Company

STEELE\_JOHN\_F@LILLY.COM



Hello everyone, my name is John Steele and today I am representing Bart Peterson, Senior Vice President of Corporate Affairs and Communications of Eli Lilly and Company, who is unable to attend due to a high level company meeting. As many of you know, Bart was recently appointed as a US ABAC member. Eli Lilly has engaged in APEC in the past and is honored to have an executive appointed as a US ABAC member. We are eager to make a strong contribution to the ABAC and leverage our expertise to advance its core objectives.

Today I would like to provide a brief overview of the health discussion taking place in APEC to give you a sense of where our expertise lies. We are new to the ABAC and are eager leverage our experience to contribute to the important work that is taking place here. We hope to follow up on this introduction at the second ABAC meeting in Singapore to explore an action plan.

## Eli Lilly & Company Overview

- Eli Lilly & Co founded in 1876
- 10th largest pharmaceutical company in the world
- Headquarters located in Indianapolis, Indiana, U.S.A.
- Approximately 38,000 employees worldwide
- More than 7,400 employees engaged in research and development, research and development facilities located in eight countries
- Clinical research conducted in more than 55 countries
- Manufacturing plants located in 13 countries
- Products marketed in 125 countries

For background, I would like to begin with a brief overview of our company. We are the 10<sup>th</sup> largest pharmaceutical company in the world with 38,000 employees worldwide. As you can see we have operations and markets in a number of countries, including several APEC economies.

## How the health industry engages in APEC

- Close collaboration with the two formal APEC bodies that co-lead the APEC health conversation: Health Working Group (HWG - government only) and Life Sciences Innovation Forum (LSIF - government, industry, academia)
- Objectives include:
  - Raising the profile of the economic burden of disease on the public and private sectors and developing solutions in close partnership with officials and business
  - Engaging in capacity building activities that help facilitate a business friendly regulatory and investment environment
  - Facilitating long term, effective, multi sectoral public private partnerships and dialogues in the region to encourage effective collaboration and the efficient use of resources

While we are new to the ABAC, Eli Lilly has contributed to the health industry's engagement in the APEC health discussion for several years. Private sector participation in this area is multi sectoral and includes companies that produce a wide array of medicines, medical devices, technologies and services.

Industry representatives collaborate closely with the two core groups that co-lead the discussion: The Health Working Group or HWG, which consists of government officials, and the APEC Life Sciences Innovation Forum or LSIF, which is a tri partite forum that includes government, industry and academia.

The business community's objectives in this area include raising the profile of the economic burden of disease on the public and private sectors and developing solutions in close partnership with officials and business, engaging in capacity building activities that help facilitate a business friendly regulatory and investment environment and facilitating long term, effective multi sectoral public private partnerships and dialogues in the region to encourage effective collaboration and the efficient use of resources.

These dialogues and partnerships range from capacity building activities with regulatory authorities to high level exchanges between APEC health ministers and CEOs.

## Prior ABAC Engagement on Health-related Issues

- Endorsement of key initiatives in the Annual ABAC Report to Leaders
- 2012 ABAC letter to Health Ministers
  - Highlighted the connection between health and economic development
  - Called for policies that encourage innovation, investment, transparency and an efficient regulatory environment

As the official mechanism for private sector input into APEC process, the ABAC has made some important contributions to the health discussion. For years, the ABAC has expressed its support for several policy objectives of the health sector in its Annual Report to Leaders, including some of the ongoing work streams that I will highlight later in this presentation.

In addition, in 2012 the ABAC set a strong precedent by conveying its views directly to APEC policy makers in its first letter to Health Ministers.

## Key Industry Issues that align with ABAC's work

ABAC's ongoing work and interests align with a number of active workstreams in the health discussion

- Investment Policy
- Regulatory Coherence
- Supply Chain Integrity/Anti-counterfeiting
- Anticorruption

There are several areas where our expertise and prior work in APEC aligns with the important work taking place in the ABAC. Our hope is to draw on our prior experience in these subject areas when contributing to ABAC's initiatives.

# Investment

- **Enablers of Investment Checklist**
- **Background:** Developed by the LSIF in 2008, the Enablers of Investment Checklist is a voluntary, self-assessment tool for policymakers in each APEC economy to assess the strengths and weaknesses of their investment environment.
- **Function:** More governments identify gaps in their regulatory environment that discourage life sciences investment by using the Enablers of Investment Checklist self-assessment tool.
- **Private sector impact:** Pro innovation environment. Increase the likelihood that governments make regulatory changes to improve their investment environment for life sciences.

The ABAC has been an effective advocate for policies that create a business friendly investment environment in the region. The APEC LSIF has engaged in a complementary effort through the Enablers of Investment Checklist it developed in close collaboration with industry in 2008.

The checklist is a voluntary, self-assessment tool for policymakers that enables them to assess the strengths and weaknesses of their life sciences investment environment. Although the checklist is designed to be sector specific, its overarching principles, such as increasing human capital, free trade and internationally harmonized regulatory systems largely align with the broader interests of the business community.

## Regulatory Coherence

- The LSIF has established the APEC Harmonization Center (AHC) and the APEC Regulatory Harmonization Steering Committee (RHSC) to address regulatory barriers in the region.
- A strategic framework to achieve Regulatory Convergence for Medical Products by 2020 was endorsed by APEC ministers in 2011. Efforts to identify policy gaps and paths to implementation are underway.
- Private sector impact: Harmonization lowers market barriers for medical products by making it easier to satisfy regulatory requirements in multiple countries without lowering safety, quality and efficacy standards. It may also help facilitate clinical research, a win-win for patients and countries seeking to attract investment.

The ABAC has also effectively championed Regulatory Coherence as part of its work to promote regional economic integration, as unnecessary differences in product regulations are a significant impediment to greater trade and investment.

In order to advance work in this area, the LSIF has established a subgroup comprised of officials, a cross section of industry experts and regulatory authorities known as the Regulatory Harmonization Steering Committee or RHSC. In addition, in 2008 South Korea committed substantial funding for the APEC Harmonization Center or AHC, which serves as the RHSC's secretariat and coordinates capacity building activities in this area.

This collaboration has resulted in a strategic framework to achieve Regulatory Convergence for Medical Products by 2020, which has been endorsed by APEC ministers and is now in the process of being implemented.

## Supply Chain Integrity/Anti-counterfeiting

- **Roadmap to Promote Global Medical Product Quality and Supply Chain Integrity**
  - Multiyear plan endorsed by the LSIF in 2012. Implementation begins in 2013
  - Will develop and implement global and regional strategies to promote medical product integrity and supply chain security for pharmaceutical medicines and medical devices.
- **Global Data Standards**
- **APEC LSIF Anti-counterfeit Action Plan**
  - Since 2008, the LSIF has organized a number of capacity building workshops to build a framework to address the global counterfeit medicine problem.
  - The workshops have resulted in increased public awareness of the issue, closer intra-governmental cooperation and formal guidelines for APEC economies.

The health care industry has a strong interest in supply chain integrity and anti counterfeit. Like many other industry sectors, the healthcare industry's supply chain has become increasingly globalized, requiring increased oversight to prevent counterfeit products, such as unsafe medicines, from reaching customers. In addition, our industry shares ABAC's interest in the role that global data standards have in ensuring efficient and safe supply chains.

To address this challenge, the APEC Regulatory Harmonization Steering Committee has secured endorsement and funding for a Roadmap to Promote Global Medical Product Quality and Supply Chain Integrity, a multi year capacity building initiative that will develop and implement global and regional strategies to promote medical product integrity and supply chain security for pharmaceutical medicines and medical devices.

A complementary effort is taking place via the APEC Anti-counterfeit Action Plan, a multiyear effort to engage government officials and industry in a series of capacity building activities targeted at addressing the challenge of counterfeit medical products. The workshops have resulted in increased public awareness of the issue, closer intra-government cooperation and formal guidelines for APEC economies.



## Codes of Business Ethics

- In 2011 Ministers endorsed three sectoral codes of business ethics to promote open and transparent business environments.
  - Hanoi Principles - construction and engineering sector
  - Kuala Lumpur Principles - medical device sector
  - Mexico City Principles - biopharmaceutical sector
- Private Sector Impact: Helps promote a level playing field for international companies and local competitors based on the same code of ethics. Encourages innovation and SME growth

Finally, I would like to conclude by highlighting the three sectoral codes of business ethics that were endorsed by the ABAC in 2011.

The voluntary codes of business ethics in the construction and engineering sector (Hanoi Principles), medical devices sector (Kuala Lumpur Principles), and biopharmaceutical (Mexico City Principles) sector will help ensure open and transparent business environments. In addition, they will promote a level playing field for large companies and SMEs and encourage innovation.

In 2013 stakeholders will work to continue implementation, code writing, and raising high-level awareness of The KL and Mexico City Principles.

## Next Steps

- Follow up discussion at ABAC II to explore next steps
- Please send your question or comments to ABAC USA at [dboman@ncapec.org](mailto:dboman@ncapec.org)



As you can see, there are a number of areas of interest to the health industry that are complementary to the ABAC's objectives. We hope to discuss how we might draw on our prior experience in APEC to contribute to the ABAC's initiatives in greater depth at the next meeting in Singapore. In the same vein, we would also like to explore how the ABAC can be supportive of the business initiatives in the APEC health discussion that align with its core objectives.

We look forward to learning from our new ABAC colleagues and encourage you to send any questions you may have to ABAC USA.

BACKGROUND ONLY – How the ABAC can be supportive of the APEC health agenda

- Greater business support for key initiatives that align with ABAC's core objectives (ie. Encouraging economies to fill out the LSIF Enablers of Investment checklist)
- Annual ABAC letter to health ministers that highlights the need for multisectoral partnerships and business friendly policies
- Business support for an institutionalized annual High Level Meeting on Health and the Economy with senior business representatives and health ministers. The first meeting in 2011 was successful, but additional meetings were only included in the 2012 and 2013 agenda after aggressive stakeholder lobbying.