APEC Business Advisory Council Serialization (ABAC) Pilot Project

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Background

• Lilly joined ABAC in 2013 as first member from the pharmaceutical industry.

• ABAC is official private sector voice in the APEC a group of 21 economies whose mission is to facilitate trade in the Asia Pacific Region.

• Pharmaceutical pilot is joining an existing list of ABAC/APEC Global Data Standards (GDS) pilot projects on other products (e.g., wine).
Strategic Goals

• Design and implement a regional pilot project in two or more APEC economies of pharmaceutical product serialization and verification through the use of GDS using GS1 standards.

• Demonstrate the benefits of using common data process approach globally for pharmaceuticals to improve patient health through the reduction of counterfeiting, speed product access to the patient, cost-savings, and help the economies become more attractive for investment.

• Inform policy, regulatory harmonization, and emerging serialization requirements for pilot economies.
Project Phases

• Phase I – feasibility analysis conducted by University of Tennessee Life Science Center. Completed (Q1 2015) and presented to:
  ✓ ABAC, APEC Life Science Innovation Forum (LSIF)
  ✓ APEC Regulatory Harmonization Steering Committee (RHSC)
  ✓ APEC Committee on Trade and Investment (CTI) in.

• Phase II – Creation, Development and Implementation of the Pilot involving 2 or more APEC economies
Current Status

• Endorsed by ABAC, APEC LSIF, RHSC, and APEC CTI

• Conceptualizing and designing possible model

• Identifying Pilot Countries (countries that have expressed interest include: Philippines, Singapore, Chinese Taipei, China, Peru, Malaysia, Thailand and Korea)
Next Steps

- Finalize model and pilot countries

- Current Company Workgroup includes: Lilly, Pfizer, EmdSerono, J&J, Abbvie, Sanofi and Bayer (BMS and Abbott as observers). We greatly welcome additional company participation

- If you are interested contact John Steele, steelejf@lilly.com