APEC Roadmap for Global Medical Product Integrity and Supply Chain Security

Seoul, 2 April 2014

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- 5 year project (Jan. 2013 - Dec. 2017)
- APEC sponsors:
  - APEC Life Sciences Innovation Forum
  - APEC Regulatory Harmonization Steering Committee (RHSC)
- Target: APEC and non-APEC regulatory authorities, industry and other relevant stakeholders
- Strategy:
  - examine current practices and regulatory requirements
  - develop recommendations to regulators
  - develop training programs which will be made publically available through the RHSC website

Track and Trace WG - GS1 involvement

- 9 topical work groups:
  - Single Point of Contact
  - Manufacturing practices
  - Clinic/pharmacy purchasing practices
  - Detection technologies
  - Internet sales
  - Distribution practices
  - Importing and exporting practices
  - Surveillance/Pharmacovigilance
  - Track and trace systems
- GS1 leads the Track and Trace Systems Work Group (TTWG)
- GS1 is a **neutral** facilitator of the WG
- Scope: pharmaceuticals

UK1

TTWG - Stakeholders involved

• Abbott	• Lilly
• Abbvie	• Merck
• Amgen	• Mylan
• Baxter	• NADFC (Indonesia)
• BMS	• Novartis
• COFEPRIS (Mexico)	• Pfizer
• EDQM – Council of Europe	• Roche
• FAHRMM	• Sandoz
• GE Healthcare	• Taiwan FDA
• J&J	• U.S. FDA

Slide 5

UK1 I will still put it in alphabetical order
Ulrike Kreysa, 19/03/2014

TTWG - Meetings Logistic

- Meetings bi-monthly via **conference calls**
  - Same call duplicated to cover different time-zones
  - Scheduled on Thursdays:

    GMT 9.30am – 10.30am

    GMT 5.30pm – 6.30pm

- **Face-to-face meetings twice per year**
  - San Francisco – September 2013
  - Seoul – March 2014

- All documents and tools available online in **APEC TTWG Community room – access only for TTWG members**

http://community.gs1.org/apps/org/workgroup/hctrackntrace/?referring_url=%2Fkws

Tools developed: TTWG Work Plan

- Listing tasks, deliverables and key milestones
- Approved by the TTWG in Nov. 2013
- To be potentially edited based on the progress of the WG

Track and Trace Systems WG Work Plan and Deliverables

The following work plan template should be used to document progress, specific tasks, and deliverables. Modify as needed to document and outline the timeline of actions the working group will be taking to meet its objectives. This should include identifying the overall objective, key steps or tasks, responsible parties, start and end dates, budget (if required), milestones, and updates.

Working Group: Track and Trace Systems

#	TASK	RESOURCE		START DATE	END DATE	MILESTONES	NOTES
		Responsible	Budget				
Start-up							
1	Project Call/Meeting Planning	GS1		26/07/2013	17/10/2013	. Bi-monthly calls : on Thursdays two calls: from 10.30am to 11.30am (CET) and from 5.30pm to 6.30pm (CET) (same duplicated at different timing) . Face-to-face meeting at the occasion of GS1 Conference	
2	Establish core WG members	GS1 + Core WG		26/07/2013	31/10/2013	. To coordinate with other participants	Potentially have MD/PH sub-groups
3	Extend active participation in the group	All		31/10/2013	End of JAN 2014	. Define list of invitees . Send invitation to PH and MD stakeholders	

Tools developed: TTWG Work Table

- Capturing the outcome of the WG discussions and findings

- Excel table with different work-sheets:
  - *« Before starting »:* description of the TTWG and the methodology
  - *« Countries List »:* countries identified by the WG as relevant (APEC and non-APEC economies)
  - *« Primary Analysis »:* overview of the requirements (regulatory and industry practice) in the relevant countries
  - *« Best Practices »:* identification of best practices

  based on the primary analysis
  - *« Glossary »*

Methodology agreed

1. identify countries of relevance of the primary analysis covering APEC economies and non-APEC economies with singular local situations

2. carry out a primary analysis of the situation in those countries covering regulatory requirements and industry practices

3. identify best practices based on the primary analysis

4. weight those best practices

5. develop recommendations and training material

1. Identify countries of relevance of the primary analysis

1. adopted requirements on pharmaceuticals traceability and/or defined implementation timelines	2. decision making and/or not yet adopted requirements on pharmaceuticals traceability	3. no requirements	4. for training
APEC economies			
India	Mexico	Australia	Brunei
China	Taiwan	Canada	Taipei
Korea	Thailand	New Zealand	Peru
Japan	Chile		Indonesia
USA	Philippines		New Guinea
Hong Kong			Singapore
			Russia
			Viet Nam
			Malaysia
non-APEC economies			
Argentina	Algeria		
Nigeria	Brazil		
Jordan	Libya		
Saudi Arabia	Egypt		
EU	Ukraine		
Turkey	Colombia		
Italy/Greece/Belgium			
France			
Cameroun			

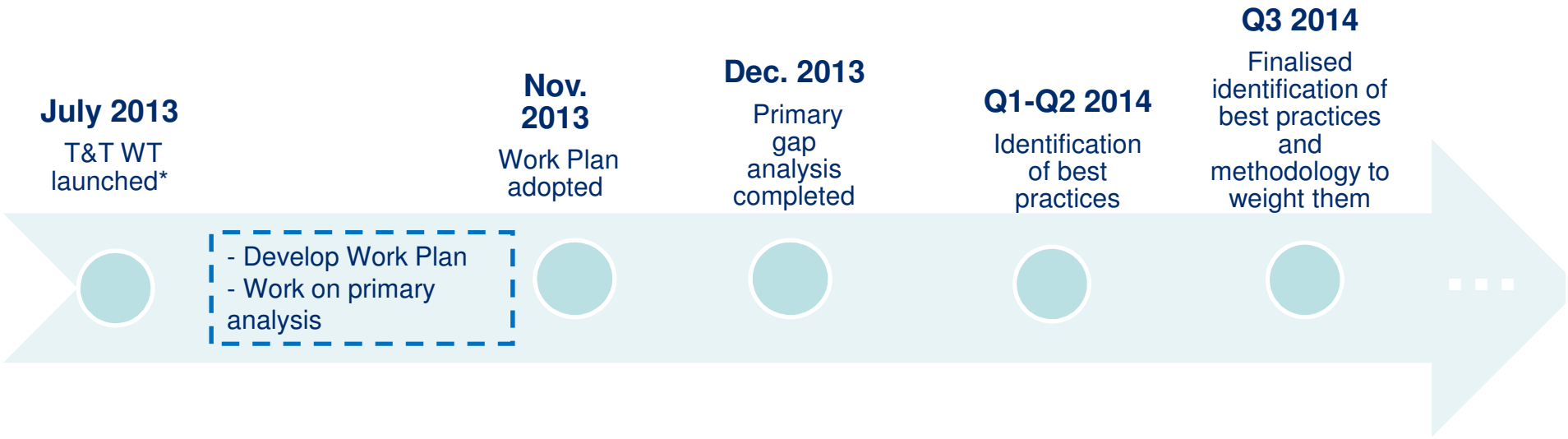
2. Carry out a primary analysis

- Going through the list of countries identified as with:
  - adopted requirements on pharmaceuticals traceability and/or defined implementation timelines
  - decision making and/or not yet adopted requirements on pharmaceuticals traceability
- Analyse the situation country by country covering both regulatory requirements and industry practices
- Capture the outcome of the analysis in an Excel Table using the GS1 hierarchy to structure the requirements:
  - Identify: refers to the data attributes assigned to a product
  - Capture: refers to the type of data carrier that the identifier is held in
  - Share: refers to data that is capture and can be shared parties within and outside of organisations across the supply chain. There are three types: Master, Transactional and Event data

3. Identify best practices based on the primary analysis

- Country by country and based on the requirements summarised in the Primary Analysis, assess:
  - what worked well
  - what could have been done better
  - what would be a recommendation
- The structure Identify/Capture/Share has been duplicated for the Best Practices identification
- A section for general comments has also been added to cover any additional thoughts

TTWG WG – Milestones 2013/14



* Bi-monthly calls and Face-to-face meetings + Regular reporting to the US FDA

Status of other work groups

- Single Point of Contact
- Manufacturing practices
- Clinic/pharmacy purchasing practices
- Detection technologies
- Internet sales
- Distribution practices
- Importing and exporting practices
- Surveillance/Pharmacovigilance

-

Next steps

- Meetings of the 9 WG's during the **2nd APEC Senior Officials Meeting (SOM II)** from 5 May to 8 May 2014 held in Qingdao, China:
  - Breakout session on the Track&Trace work group
  - Opportunity to engage directly with APEC representatives

- Face-to-face meeting : Copenhagen – October 2014

- Q4 2014: Develop recommendations and training kits based on best practices

Contact Details

Géraldine Lissalde-Bonnet
GS1 Global Office, Brussels
E g.lissalde@gs1.org
T +32-2 788 78 87
www.gs1.org/healthcare