STG (U&N)

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AHWP 21st Annual Meeting
November 24, Cebu

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

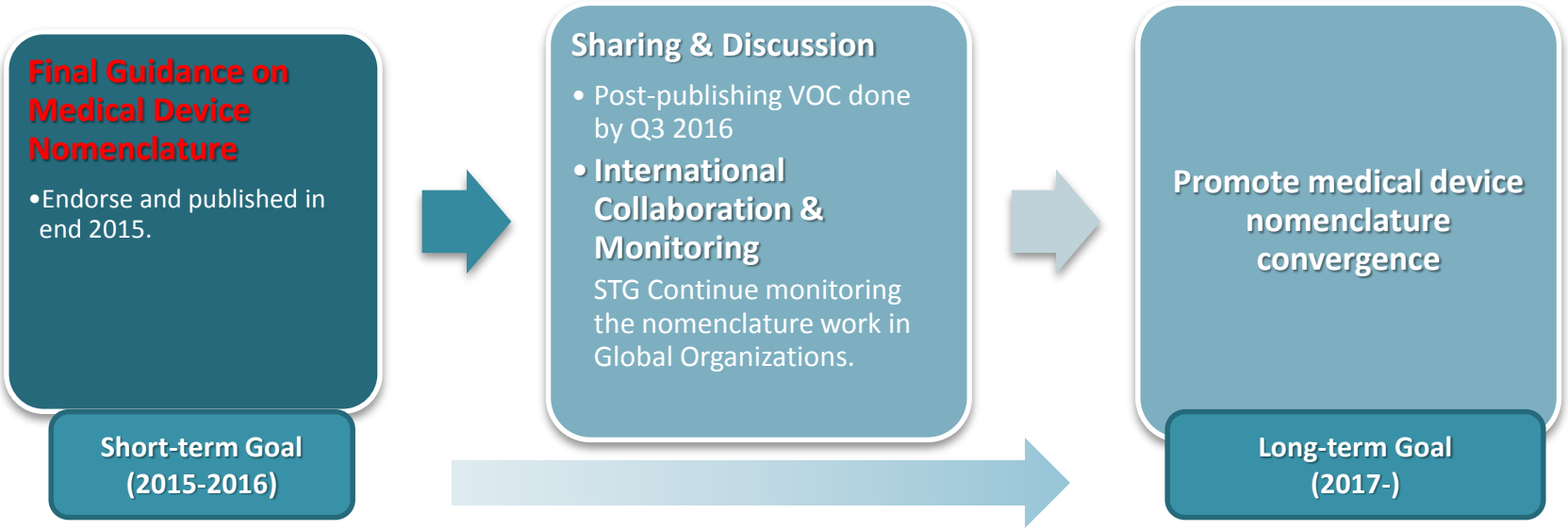
Agenda

- Membership Status
- Nomenclature Update
- UDI Update
- Next step

Membership

- Review and valid active members
  - Regulator: 8 (China, Saudi Arabia, Singapore, S. Korea, Thailand)
  - Industry: 19
- Member Economies:
  - China, Chinese Taipei, HongKong, Saudi Arabia, Singapore, South Korea, Thailand

Status of WG Items -Nomenclature



Other Work in Progress	
1.	China as a key member of STG will continuously work on Medical Device Naming Catalogue and Naming Guidance, share experience learn from these initiative to STG members.
Action Plan	
1.	STG will continuously involve in the harmonization work in device nomenclature.
2.	STG will further understand the current status in medical device naming in member economies and look for piloting opportunities to promote medical device nomenclature convergence.

Status of WG Items – UDI

UDI CAN HELP

✓Quick identification

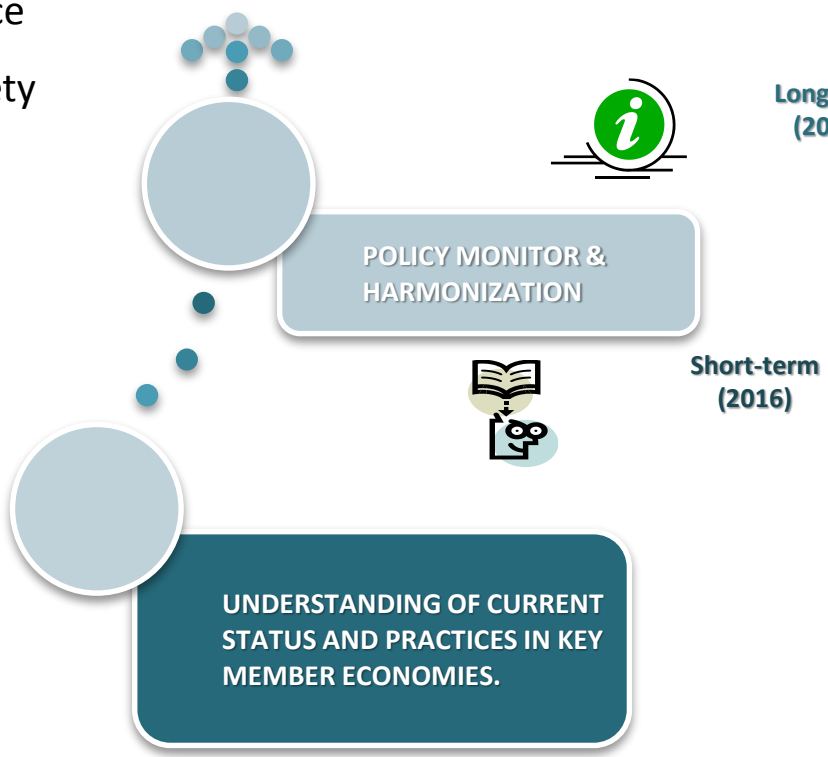
✓Control the Risk of the Device

✓Ensure the supply chain safety

✓Protect the patient and consumers

Hot Topic

STG PROVIDES CONTINUOUS GUIDANCE TO THE AHWP MEMBER ECONOMIES ON THE HARMONIZED APPROACH OF THE UDI SYSTEM.

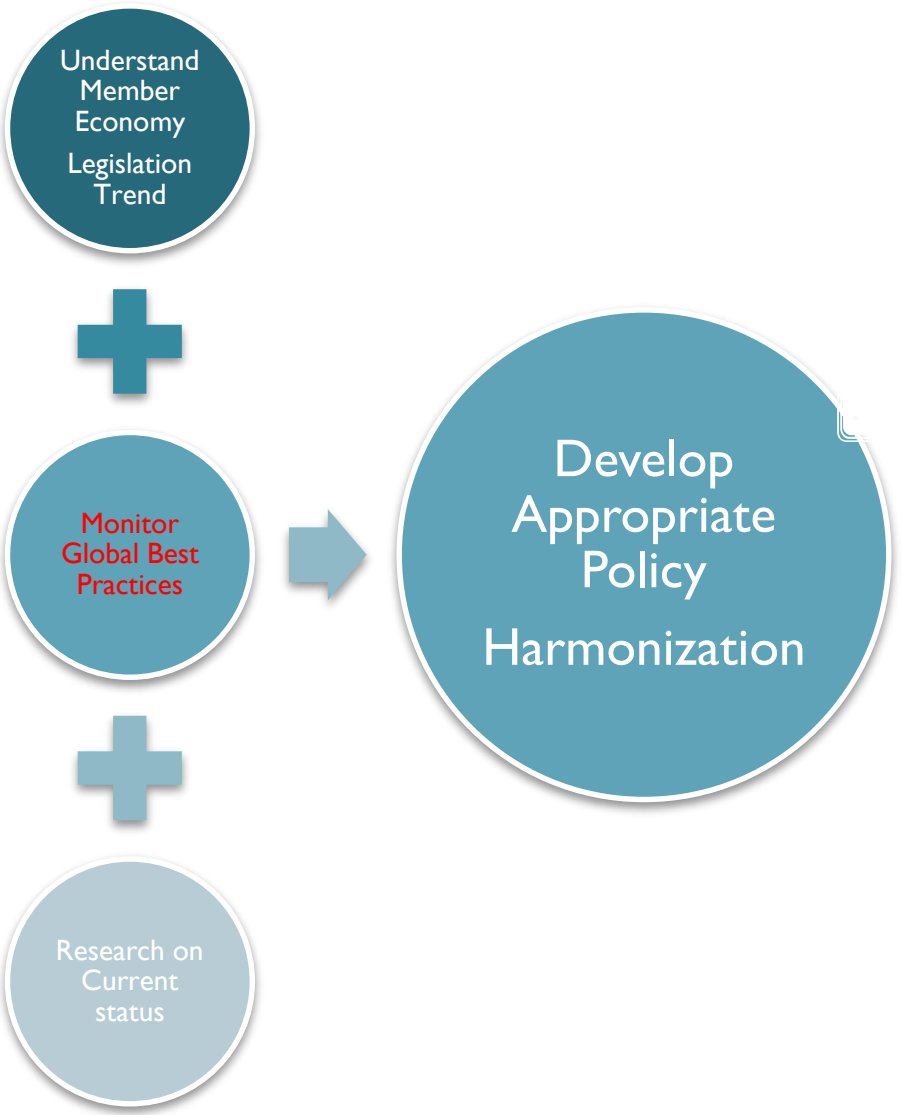


UDI Investigation & Develop Pathway in China
- For AHWP Member Economy Reference

CFDA opinion on promoting the food and drug manufacturer and distributor to build up a tracing system

Pay close attention to global progress of UDI, incl. IMDRF, USA , EU

- Demand from Manufacturer and hospital;
- Pilot project on UDI initiated by PLA hospital



Next Step

International Collaboration

- STG is monitoring device Nomenclature and UDI update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and EU DG GROW , etc.

Regional Support

- STG continuously follow member economies on Nomenclature and UDI development status, and provide support as necessary to ensure the harmonization with global model.

Country Specific Piloting and Research

- STG is continuously working on **Nomenclature** and **UDI Rules** in member economies. Such as start feasibility study for selected product types in 2017 and onward.

ASIAN HARMONIZATION WORKING PARTY

Thank you