AHWP TC

PROPOSED STRATEGIC PLANNING FOR DISCUSSION

Asian Harmonization Working Party (AHWP)

- Asian Harmonization Working Party (AHWP)

Established as a non-profit organization.Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

- Vision

To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry in Asia and other continents.

- Mission

To Strategically Accelerate Medical Device Regulatory Convergence through Promotion of an Efficient and Effective Regulatory Model for Medical Devices.

GOALS

GOAL1

- To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

GOAL2

- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

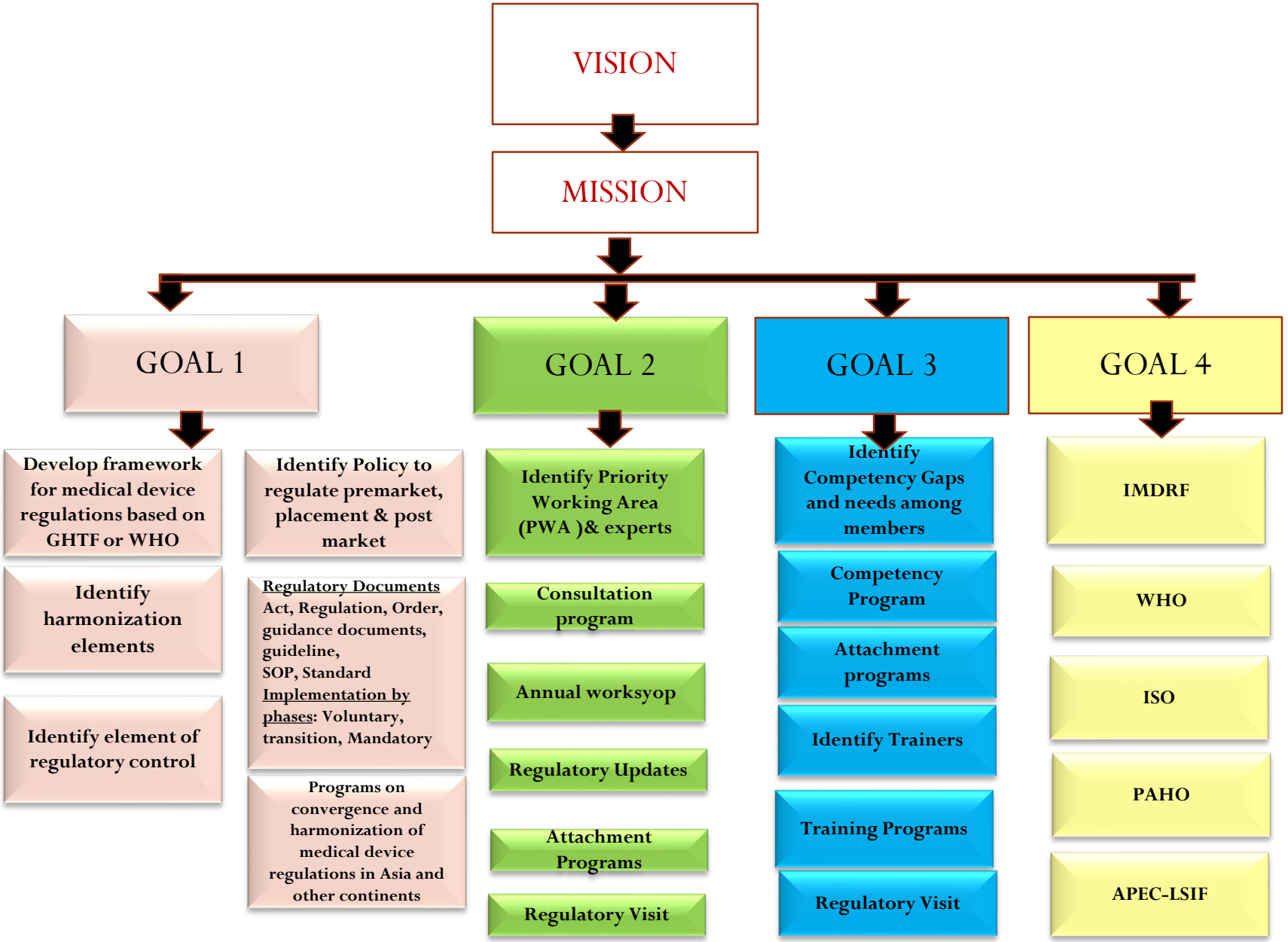
GOAL3

- To promote capacity building in member economies and to foster strategic membership expansion.

GOAL4

- To work in collaboration with related international organizations such as International Medical Device Regulators Forum(IMDRF), WHO, ISO, IEC.

STATEGIC PLAN 2019-2020?



GOAL1:To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

I. DEVELOP FRAMEWORK FOR MEDICAL DEVICE REGULATIONS BASED ON GHTF ,IMDRF or WHO

- Premarket
  - QMS manufacturing activities
  - Testing
  - Clinical evaluation/clinical trial
- Placement
  - Establishment Licence
  - QMS for import/distribution
  - Product registration
  - Advertisement
- Post market
  - Recall
  - Distribution record
  - FSCA
  - Adverse event reporting
  - Auditing/Inspection

- IDENTIFY REGULATORY FRAMEWORK(ADOPTION OF PLAYBOOK as reference **good medical device regultory framework**
- IDENTIFY GAP
- DEVELOP IMPLEMENTATION PLAN

II) **IDENTIFY HARMONIZATION ELEMENTS**

- Medical device definition,
- classification,
- ESSENTIAL PRINCIPLES OF SAFETY & PERFORMANCE (EPSP)
- risk classification,
- COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)csdt,
- standards for premarket,placement & postmarket

III) **IDENTIFY REGULATORY ACTIVITIES** under premarket,placement and post market, requirements, GD and relevant standards

- Premarket-
  - manufacturing activities QMS ISO13485
  - preclinical testing ISO10993
  - Clinical trial ISO14155
  - Testing
- Placement
  - Registration of medical device
    - Conformity assessment procedures ISO17021
    - Assessments of MD based on EPSP
    - CSDT
    - Classification of MD
    - A bridge method of product verification
    - Special access
  - Establishment licence
    - QMS
    - GDPMD
  - Advertisement
- Post market
  - Distribution record
  - FCA
  - Recall
  - Mandatory problem reporting
  - Complaint handling
  - Maintenance
  - Disposal

IV) IDENTIFY POLICY TO REGULATE PREMARKET, PLACEMENT & POST MARKET (BY MEMBER ECONOMIES)

V) REGULATORY DOCUMENTS

- **Act, Regulation,Order,**
- **GUIDANCE DOCUMENTS BY WG AHWP**
- **Guideline,SOP,Standard**
- **Regulatory Impact Study**
- **Good regulatory Practice(GRP)**
- **Implementation by phases: Voluntary, transition, Mandatory**

VI) Programs on convergence and harmonization of medical device regulations in Asia and other continents.

a) Surveys on regulatory requirements based on framework

-identify regulatory requirements in member economies

-Current status

-identify gaps

b) Harmonization WP

To identify among member economies adoption of

- Definition MD
- Risk Classification ABCD, AMDC template
- CSDT- ACSDT template
- EPSP/standard-

c) Adoption of AHWP/IMDRF GD

d) Impact study

e) GRP

f) Propose models :Voluntary, transition, Mandatory

GOAL 2

To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

- Identify Priority Working Area (PWA)& experts(champion economy-member economy)
  - QMS
  - Product registration
  - Testing
  - Post market
- Attachment programs for regulators
- Country representative updates the secretariat
- Annual workshop to identify workprogram
- Regulatory updates during meeting
- Consultation Program: to provide assistance to develop regulatory document /system based on IMDRF/AHWP(WG)
- Regulator Visitation Program

GOAL 3

To promote capacity building in member economies and to foster strategic membership expansion.

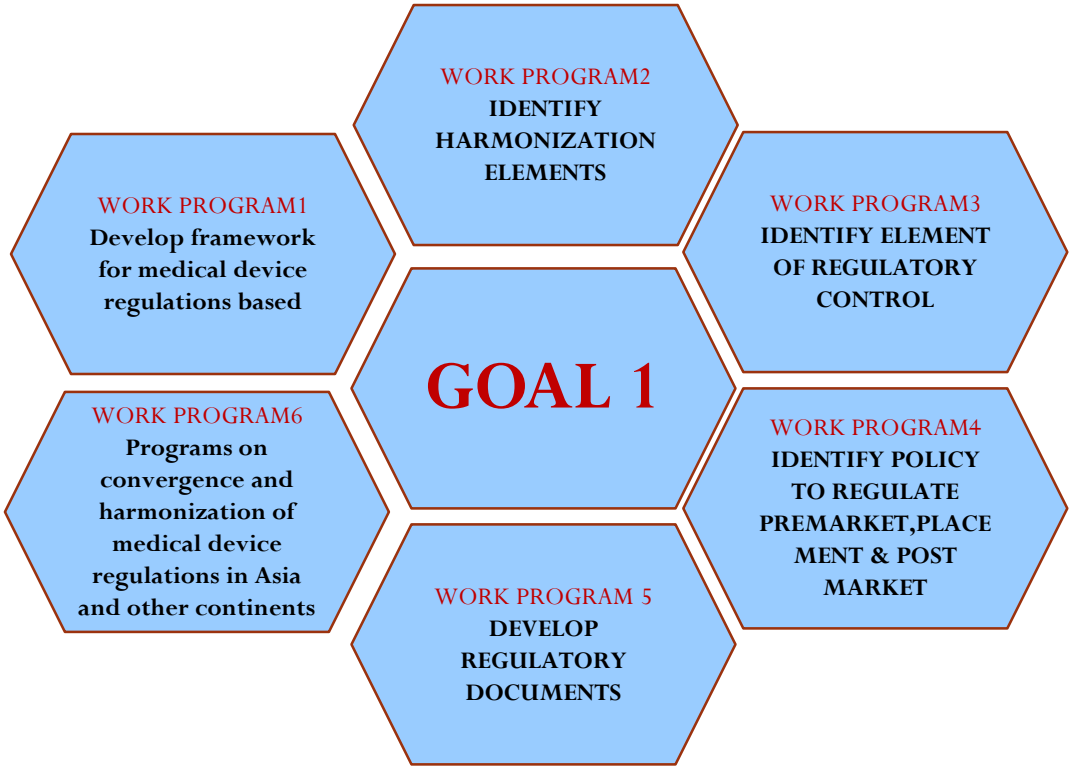
- Survey among member economies (country representatives to update)
- Identify Gaps and needs among member state
- Develop competency program
- Develop curriculum for regulator/industry
- Identify Trainers (CORE) among member economies-AHWP
- List of training module
- Training program -In house/Regional
- Updates of member economies
- Updates on IMDRF member economies regulatory training/attachment
- IMDRF expert training

GOAL 4

To work in collaboration with related international organizations such as International Medical Device Regulators Forum(IMDRF), WHO, ISO, IEC.

- AHWP Representative in IMDRF,WHO,ISO/IEC,PAHO,APEC-LSIF
- Participation in WP
- Reporting/updates during AHWP meeting

PROPOSED WORKPROGRAM FOR GOAL 1



PROPOSED WORKPROGRAM FOR GOAL 2

PROPOSED WORKPROGRAM FOR GOAL 3

PROPOSED WORKPROGRAM FOR GOAL 4(EXISTING COLLABORATION)

Thank you