AHWP SURVEY REPORT

I. OBJECTIVE

The AHWP survey is conducted to gain insight into the medical device pre-market submission requirements of member economies and to collate the various requirements and documentation. Input from member economies will be used by AHWP Technical Committee as collaborative regional harmonization effort to lay out preparatory work plan for a common pre-market submission dossier.

II. INTRODUCTION

- The AHWP survey form was distributed to 11 member economies:

1. Brunei
2. China
3. Hong Kong
4. India
5. Indonesia
6. Korea
7. Malaysia
8. Philippines
9. Singapore
10. Taiwan
11. Thailand

- The completed survey forms were received from 6 member economies:

1. Hong Kong
2. Korea
3. Malaysia
4. Philippines
5. Singapore
6. Thailand

The percentage of respondents is 54.5%.

III. DISCUSSION

- **Table 1:** Out of these 6 member economies, marketing clearance for medical devices is not required in Hong Kong. Among the 5 member economies where marketing clearance is required, the process is not fully operational in 2 member economies, Singapore and Malaysia.

- **Table 2(i), (ii):** Among the 5 member economies where marketing clearance for medical devices is required, 4 member economies subject devices to more than 1 possible pathways for marketing clearance depending on the device classification. Philippines and Thailand (2 member economies) issue marketing clearance through 3 different pathways. Philippines subject devices to pre-market approval, pre-distribution notification or post-notification. Thailand requires pre-market approval for licensable devices, pre-distribution notification for listable devices and submission of a certificate of free sales for general devices. Korea and Singapore (2 member economies) subject devices to pre-market approval or pre-distribution notification (2 pathways). Malaysia (1 member economy) has only 1 pathway for marketing clearance of devices emitting ionizing radiation, which is pre-market approval. The pre-market approval pathway is required by all 5 member economies.

- **Table 3(i), (ii):** Among the 5 member economies where marketing clearance for medical devices is required, a format and guidance on how to prepare the dossier of support documents for pre-market submission is available for all 5 member economies. Malaysia and Thailand (2 member economies) require the submission of full technical documentation. Korea, Philippines and Singapore (3 member economies) require the submission of summary technical documentation.

- **Table 4:** Among the 5 member economies where marketing clearance for medical devices is required, the extent of data documentation to be submitted depends on the complexity and risk class of the device for 4 member economies, except Thailand.

- **Table 5:** There are 31 elements of the STED. Among the 5 member economies where marketing clearance for medical devices is required, 4 member economies require the submission of >70% of the elements, namely Korea (83.9%), Philippines (93.5%), Singapore (93.5%) and Thailand (71.0%). Malaysia requires 45.2%, comparatively, the least of the STED elements.

IV. SUMMARY

The survey analysis has demonstrated that marketing clearance for medical devices is required in 5 of the 6 member economies, which responded to the survey, namely, Korea, Malaysia, Philippines, Singapore and Thailand. Most of the documentation data for pre-market submission in these member economies is similar to the elements of STED. Of these member economies, Korea, Philippines and Singapore, provided submission guidelines. Table 6 shows that the additional non-STED documentation required by these 3 member economies are minimal. This is indicative of the potential usefulness of STED in serving as a harmonized pre-market submission guideline for the preparation of documentation data in Asia.

Table 6

Submission of non-STED documentation		
Korea	**Philippines**	**Singapore**
1. Storage condition after use 2. Precautions 3. Warning 4. Shelf-life 5. Conditions for conservation 6. Catalogue	1. Representative sample 2. Commercial presentation of sample	1. Precautions 2. Warning 3. Potential adverse events 4. Promotional material