
# *Survey Report*

# *AHWP Survey Objectives*

- **Gain insight into the medical device pre-market submission requirements of member economies**
- **Collate the various documentation requirements**
- **Lay out the preparatory work plan for a common pre-market submission dossier**

# *AHWP Survey Response*

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

The AHWP survey form was distributed to **11** member economies

# *AHWP Survey Response*

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

The AHWP survey form was distributed to **11** member economies

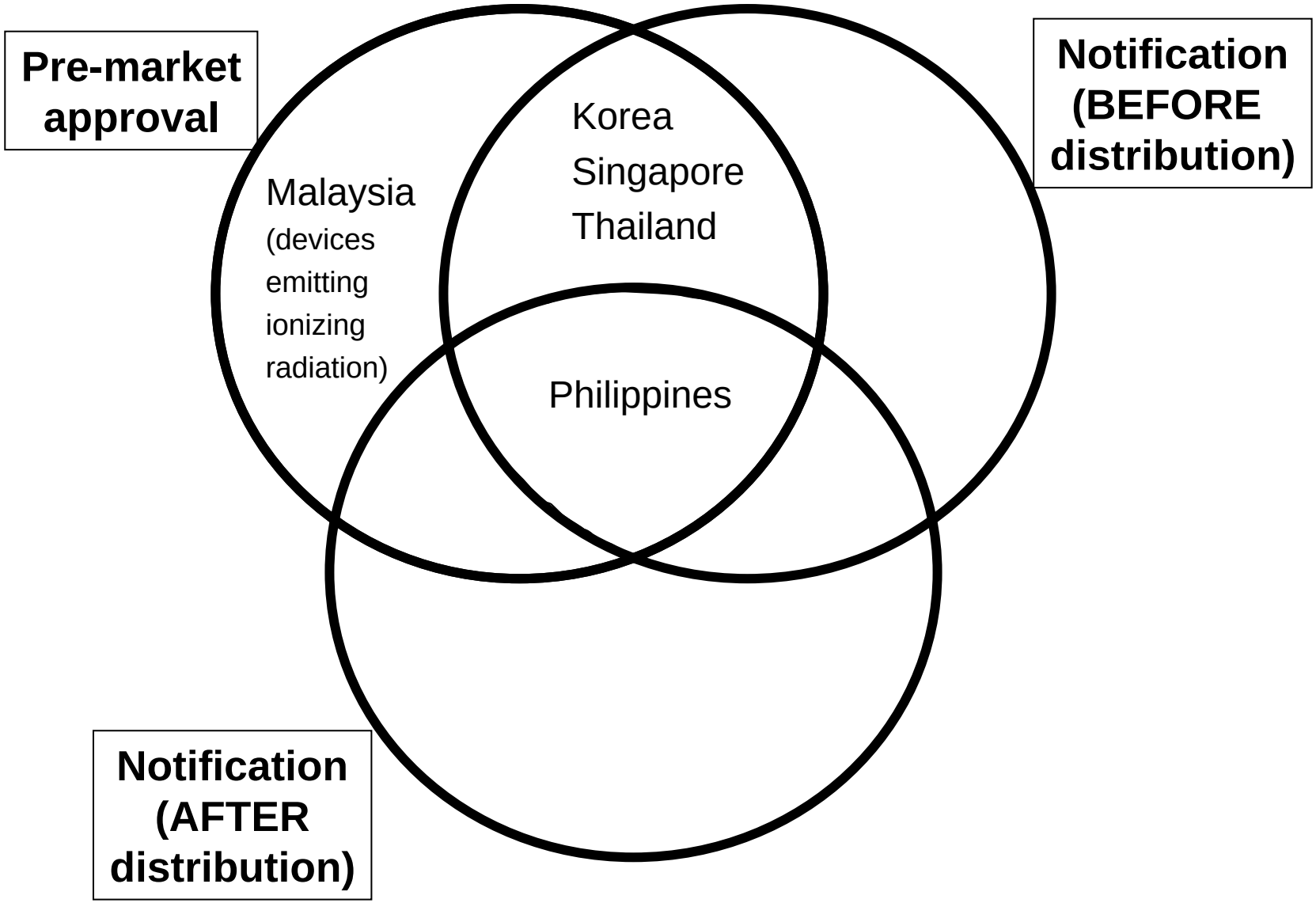
The completed survey forms were received form **6** member economies

# *AHWP Survey Analysis*

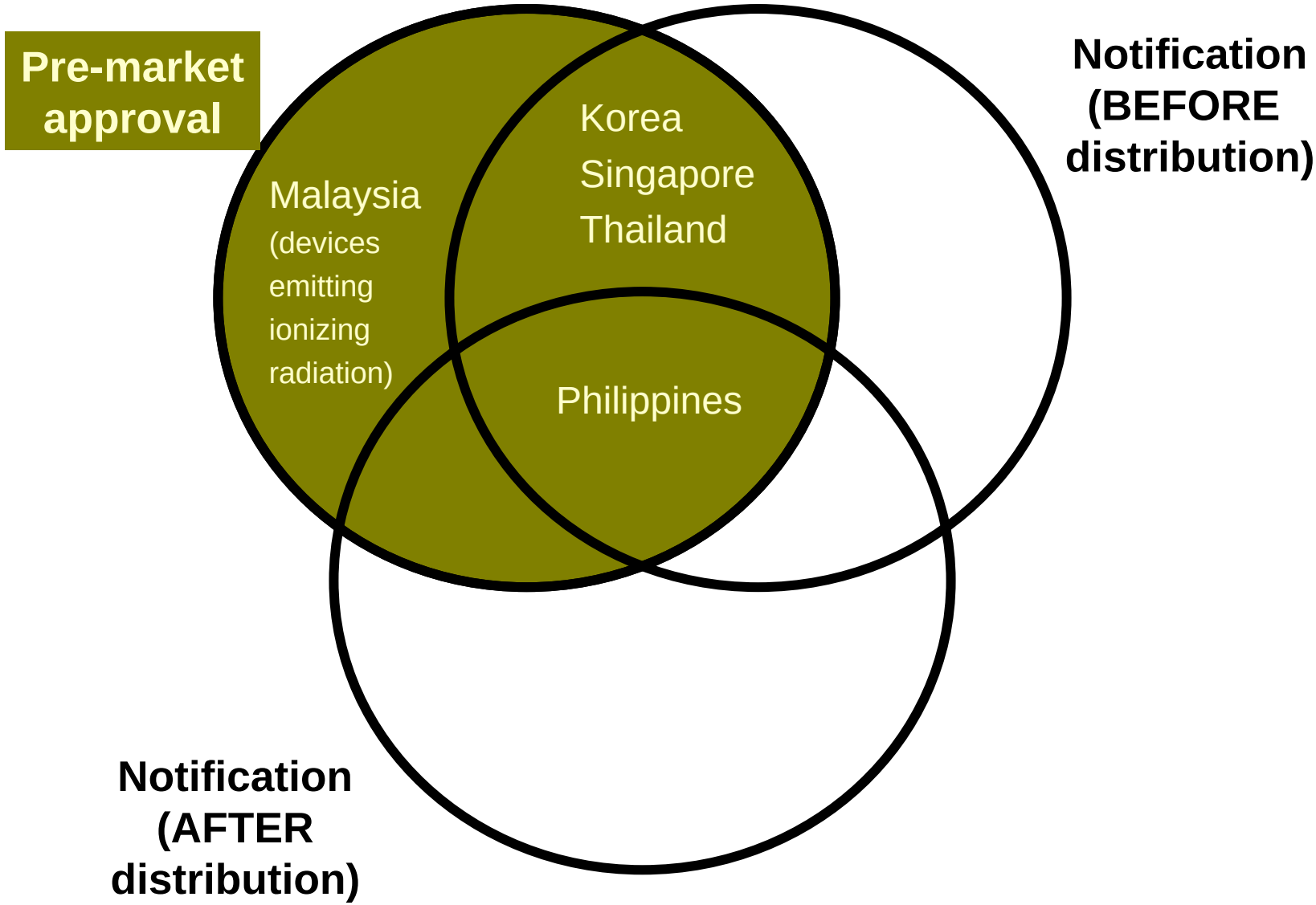
1. Hong Kong
2. Korea
3. Malaysia
4. Philippines
5. Singapore
6. Thailand

**MARKETING CLEARANCE FOR MEDICAL DEVICES**

# *Different pathways for obtaining marketing clearance*



# *The pre-market approval pathway is required by all 5 member economies*



# *Support document format for pre-market submission*

**Full technical documentation**

**Malaysia**
**Thailand**

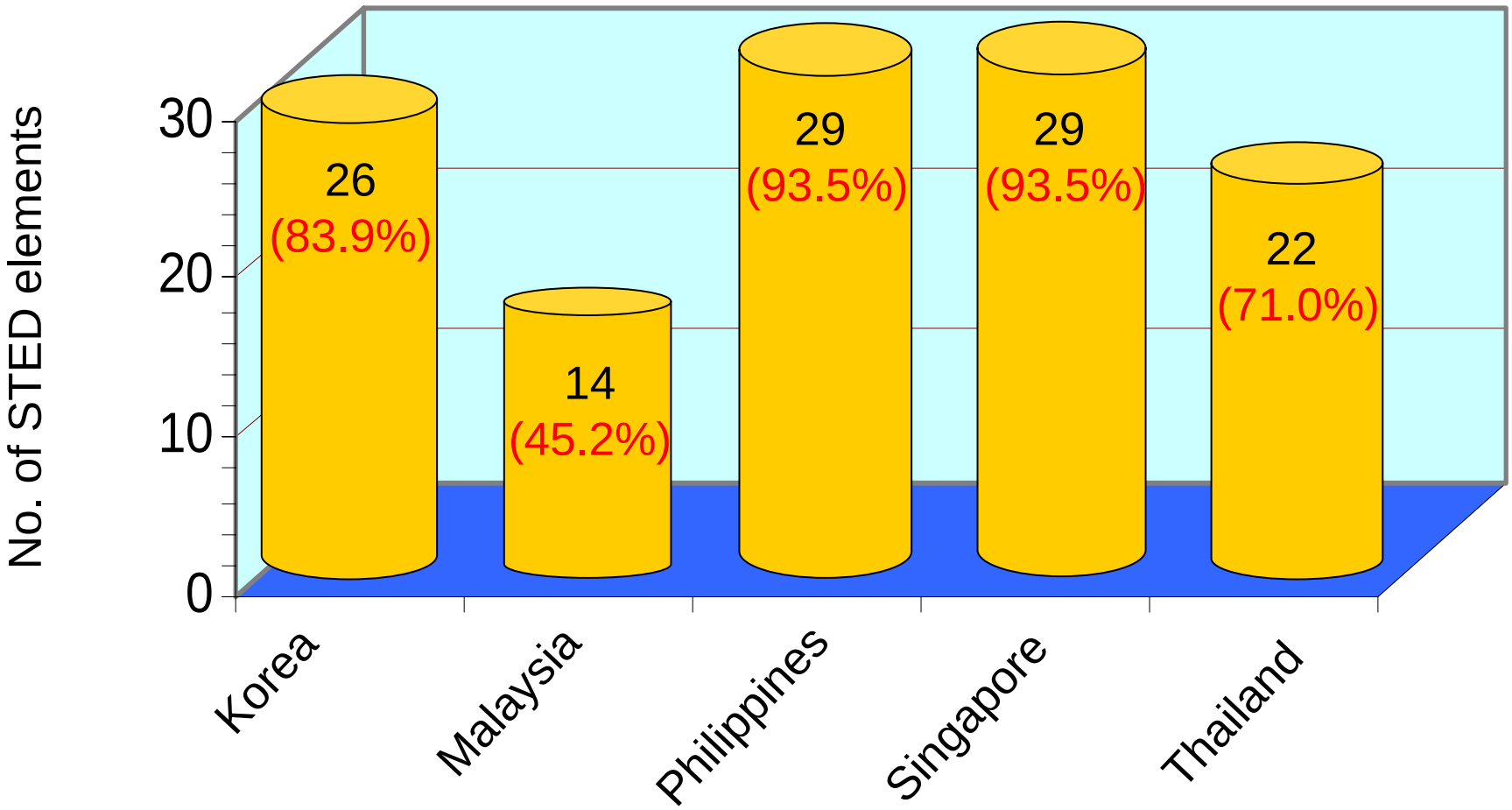
**Summary technical documentation**

**Korea**
**Philippines**
**Singapore**

***The extent of data documentation to be submitted depends on the complexity and risk class of the device for 4 member economies, except for Thailand.***

# Documentation of data according to STED elements

**There are 31 elements of the STED**



# *Submission of non-STED documentation*

| Korea | Philippines | Singapore |
|---|---|---|
| 1. Storage conditions after use<br>2. Precautions<br>3. Warning<br>4. Shelf-life<br>5. Conditions for conservation<br>6. Catalogue | 1. Representative sample<br>2. Commercial presentation of sample | 1. Precautions<br>2. Warning<br>3. Potential adverse events<br>4. Promotional material |

## *Summary*

# **Additional non-STED documentation required by these 3 member economies are minimal**

# **indicative of the potential usefulness of STED in serving as a harmonized guideline for the application of medical device marketing clearance in Asia.**