AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Summary and Comparison on Regulatory Framework of Medical Devices

AHWP Secretariat

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Purpose and Objectives of Comparison Study

The study is to promote communication and assess progress on regulatory convergence annually

Objectives:

- **Collect data and information on the control of medical devices in AHWP member economies**
- **To present an overview of the Asian medical devices regulatory requirement**
- **To assess its situation and trend in terms of the framework of control; and**
- **To identify issues related to the harmonization of Asian medical devices regulatory requirement and to make recommendations as to how the harmonization can be best achieved.**

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What to Know from the Survey and annual summary

- Status of establishment of regulatory framework, such as authorities, legislation, national policies and standards, and regulatory capacity
- Current regulatory requirements and practice for premarket approval, post-market surveillance, QMS and conformity assessment
- Status of adoption of GHTF Documents and AHWP guidance such as definitions and classification
- Market size or trade information if possible?

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Methods of the Comparison Study

	Tasks	Timeline
1	**Work team building up**	Feb 09
2	**Questionnaire re-design, based on the survey done previously**	Mar 09
3	**Comments from member economies on questions**	Apr-May
4	**Discussion for improvement and equal understanding of the questions**	Jun-Jul
5	**Distribution of final questionnaire**	Aug 09
6	**Questionnaire collection and phone inquiring**	Sep-Oct
7	**Statistics, analysis and summary**	Oct 09
8	**Study report and presentation**	Nov 09

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Questionnaire designed with 6 sections

The survey forms have been sent to 17 member economies and 14 of members have responded so far as yesterday

Section	Content	Number of Questions
1	General	9
2	Pre-Market Stage	7
3	Labeling, Advertising and distributing	3
4	Post-market Stage	4
5	Regulatory Authority	5
6	Organizational Development	2
	Total	30

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17 AHWP Member Economies cover 3bi population

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Sec 1: General

11 members economies have an existing regulatory system, among them,

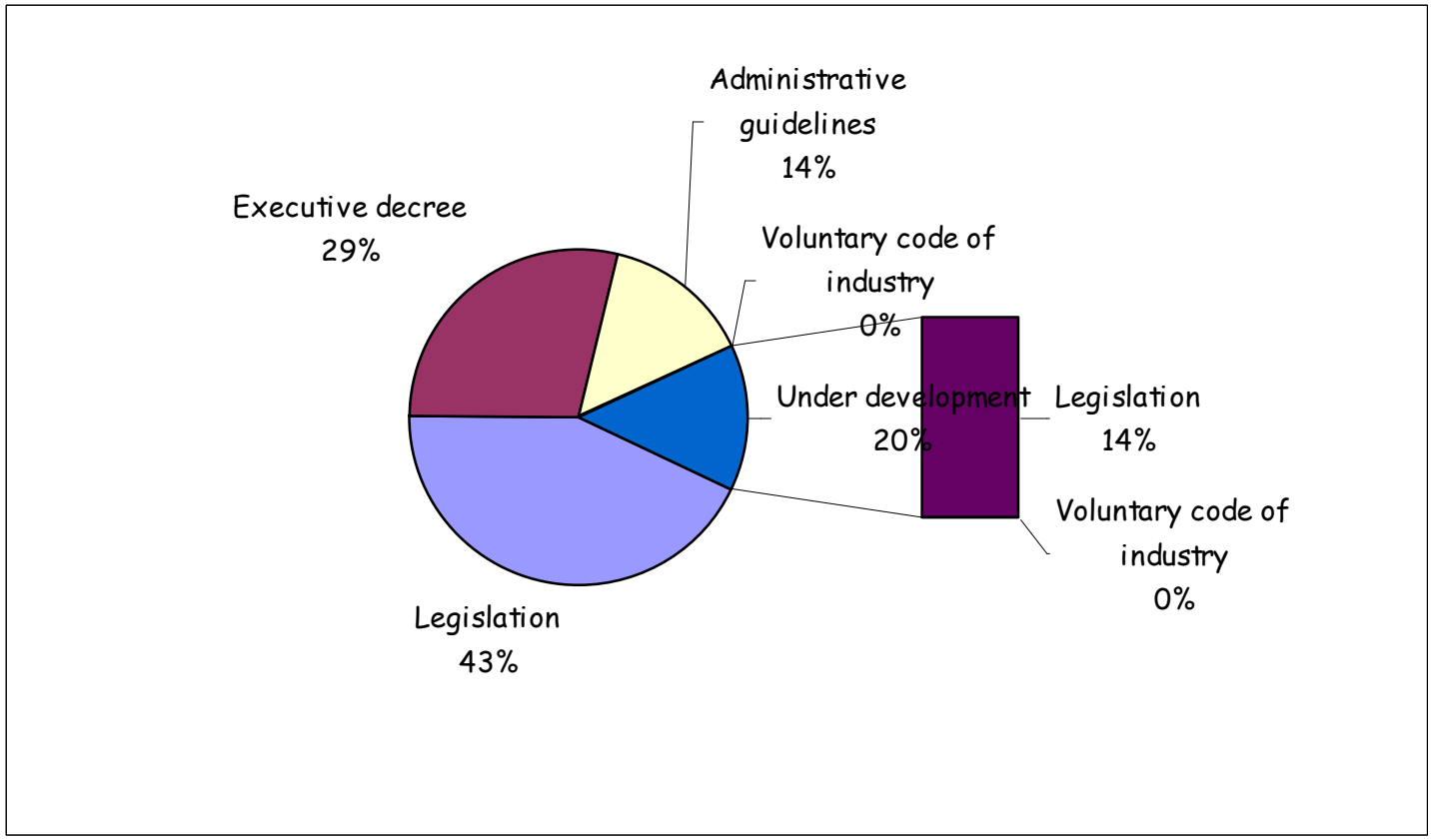
6 with legislation,

4 with Executive decree and

2 with administrative guidelines.

4 are under development

Q1: the nature of existing regulatory system



11 AHWP Members with Controls on Medical Devices

11 AHWP Member Economies have regulatory controls on medical devices, in 14 responders

No	Member Economies	Pop /mil	Legislation (Yes/No)	Executive Decree(Y/N	Admin Guideline(YN	Voluntary Code (Y/N)	Under Developing
1	Singapore	5	2007-07		2007-11		
2	Saudi Arabia	23		2008-12			
3	South Africa	46					currently
4	Korea	49		2003			
5	China	1300		2000-04			
6	Malaysia	23					currently
7	India	1030	1945				
8	Chinese Taipei	20	1970-07				
9	Hong Kong	6			2004-11		
10	Thailand	63	1988				
11	Philippines	83	2009-12?				
12	Indonesia	215		2002			
13	Vietnam	80					
14	Myanmar	52					
15	Cambodia	13	1997				
16	Laos	6					2010?
17	Brunei	0.4					

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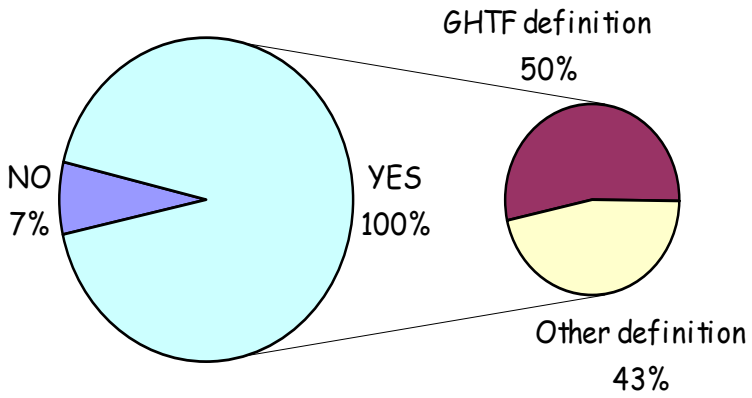
Total	3,014

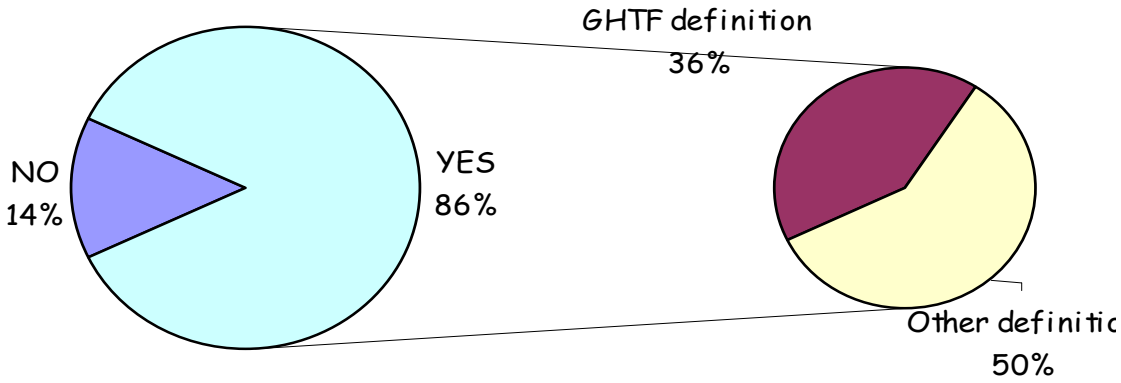
- All 13 member economies have established the Definition for medical devices,
  Half have applied GHTF definition, and
  Another half use other definitions e.g. referenced to FDA's

Q3: Is Definition of Medical Devices established? GHTF or other?



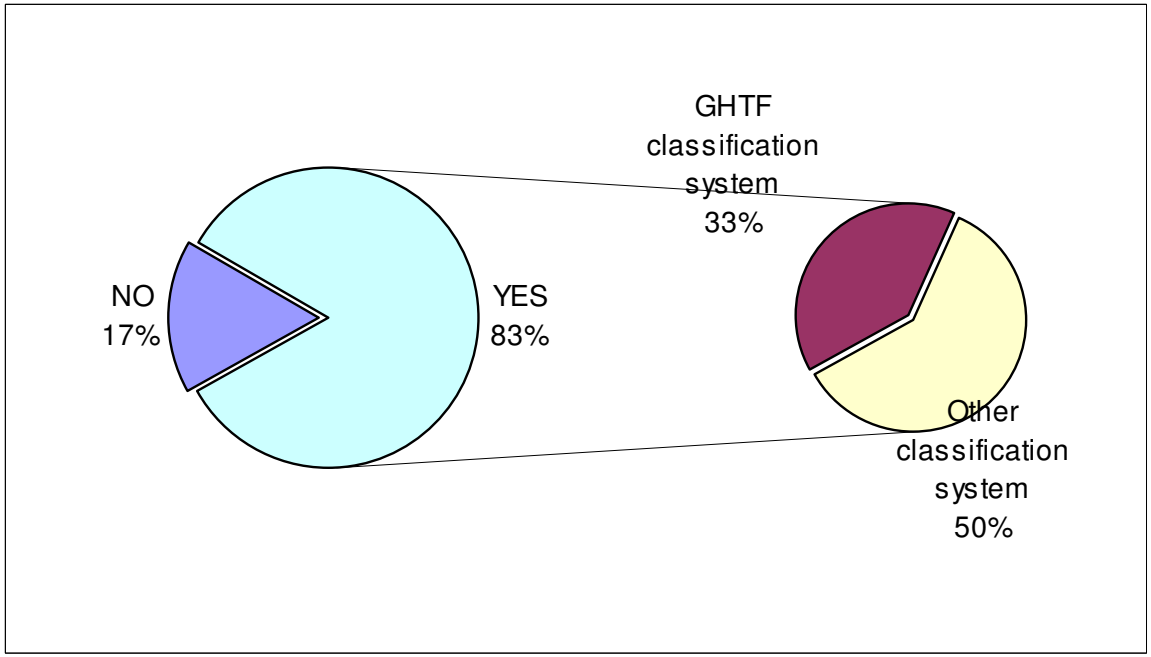
11 members economies have established the definition for manufacturer,
4 members have already used GHTF definition,
7 use other definitions

Q4: Is definition of manufacturer established? GHTF or other?



10 members economies have established the classification system,
4 of them have already used GHTF classification

Q5: Is a Classification System established? GHTF or other?



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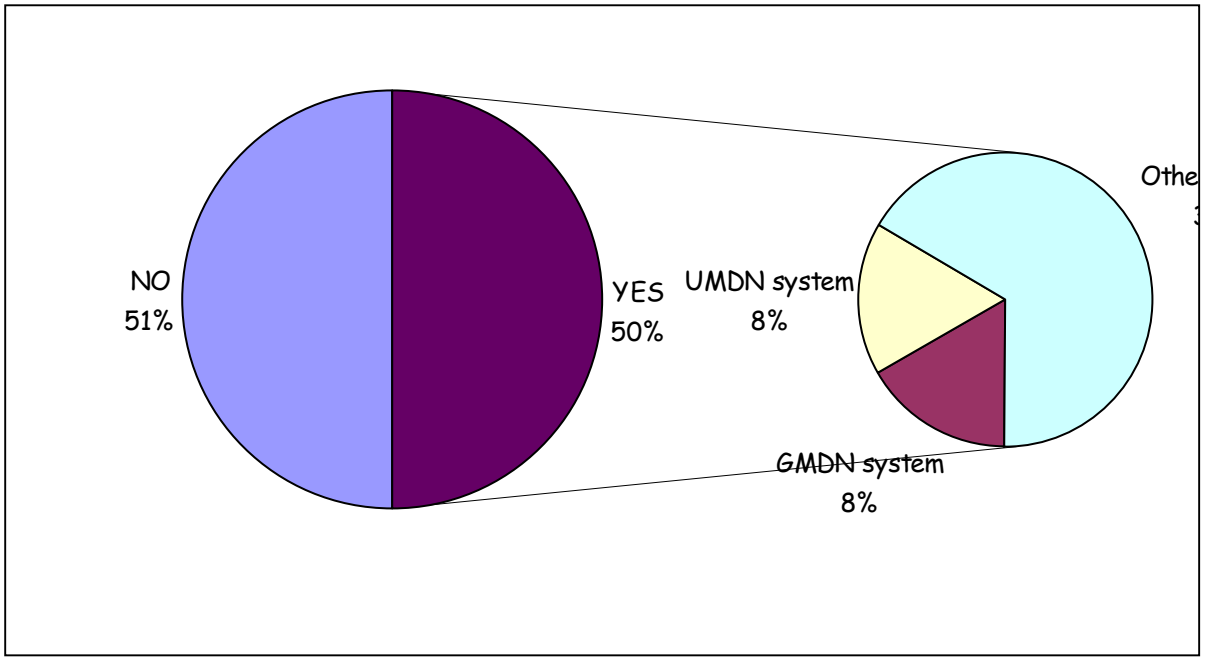
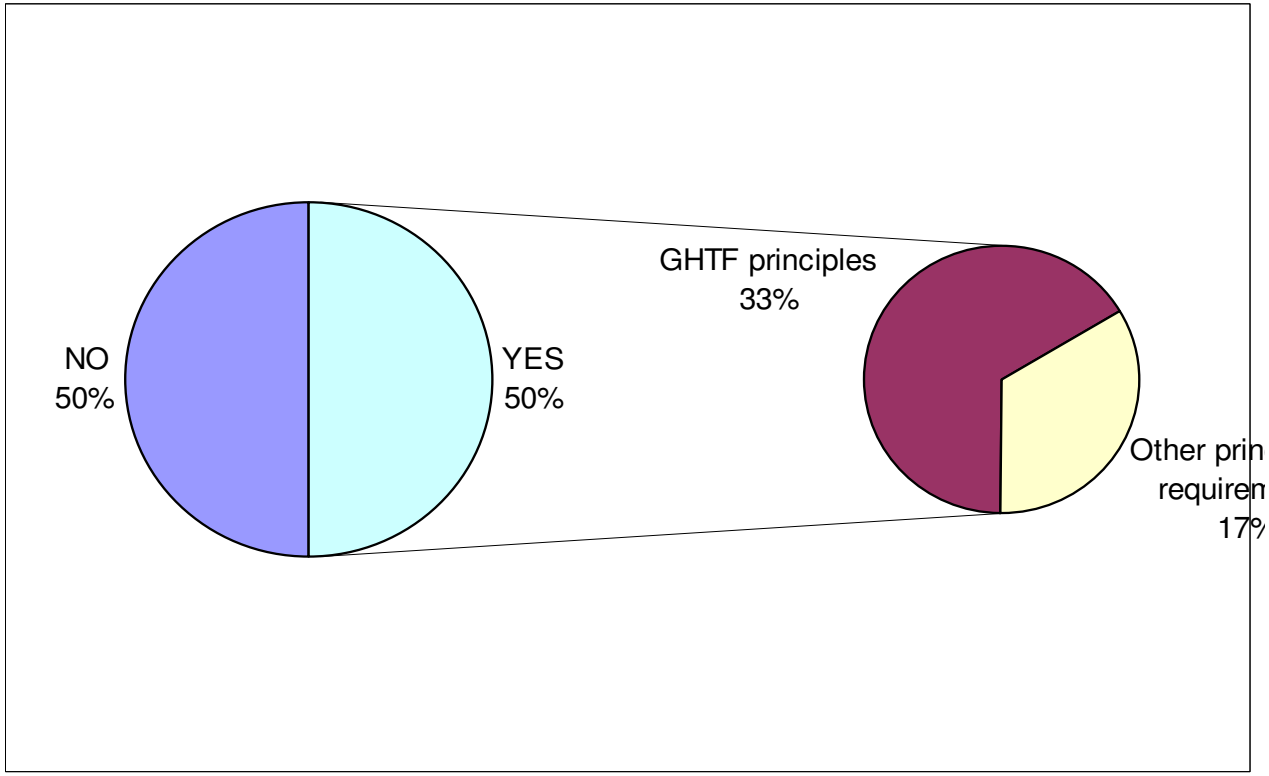
6 members economies have established nomenclature system,
1 of them uses GMDN, another uses UMDN,
4 of them use other systems

Q6: Is Nomenclature System established?



6 members economies have established the essential principles for safety and performance,
4 of them have already used GHTF essential principles,
8 have not yet

Q7: Essential Principles of Safety and Performance? GHTF or other?



Q3-7: Many members have adopted GHTF definitions of MD, manufacturer, Classification or essential principles

No	Member Economies	Pop /mil	Medical Device	Manufacturer	Classification	Nomenclature	Essential Principles
1	Singapore	5	Yes, GHTF	Yes	Yes, GHTF	Yes, GMDN	Yes, GHTF
2	Saudi Arabia	23	Yes, GHTF	Yes, GHTF	Yes, GHTF	No	Yes
3	South Africa	46	Yes	Yes	No	No	No
4	Korea	49	Yes	Yes	Yes	Yes	Yes
5	China	1300	Yes	No	Yes	No	No
6	Malaysia	23	Yes, GHTF	Yes, GHTF	Yes, GHTF	No	Yes, GHTF
7	India	1030	Yes	Yes	No	No	No
8	Chinese Taipei	20	Yes	Yes	Yes	Yes	No
9	Hong Kong	6	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes	Yes, GHTF
10	Thailand	63	Yes, GHTF	Yes	Yes	Yes, UMDN	No, (GHTF)
11	Philippines	83	Yes	Yes	Yes	No	No
12	Indonesia	215	Yes, GHTF	Yes, GHTF	Yes	Yes	Yes, GHTF
13	Vietnam	80					
14	Myanmar	52					
15	Cambodia	13	Yes	Yes	No	No	No
16	Laos	6	No	No	No	No	No
17	Brunei	0.4					

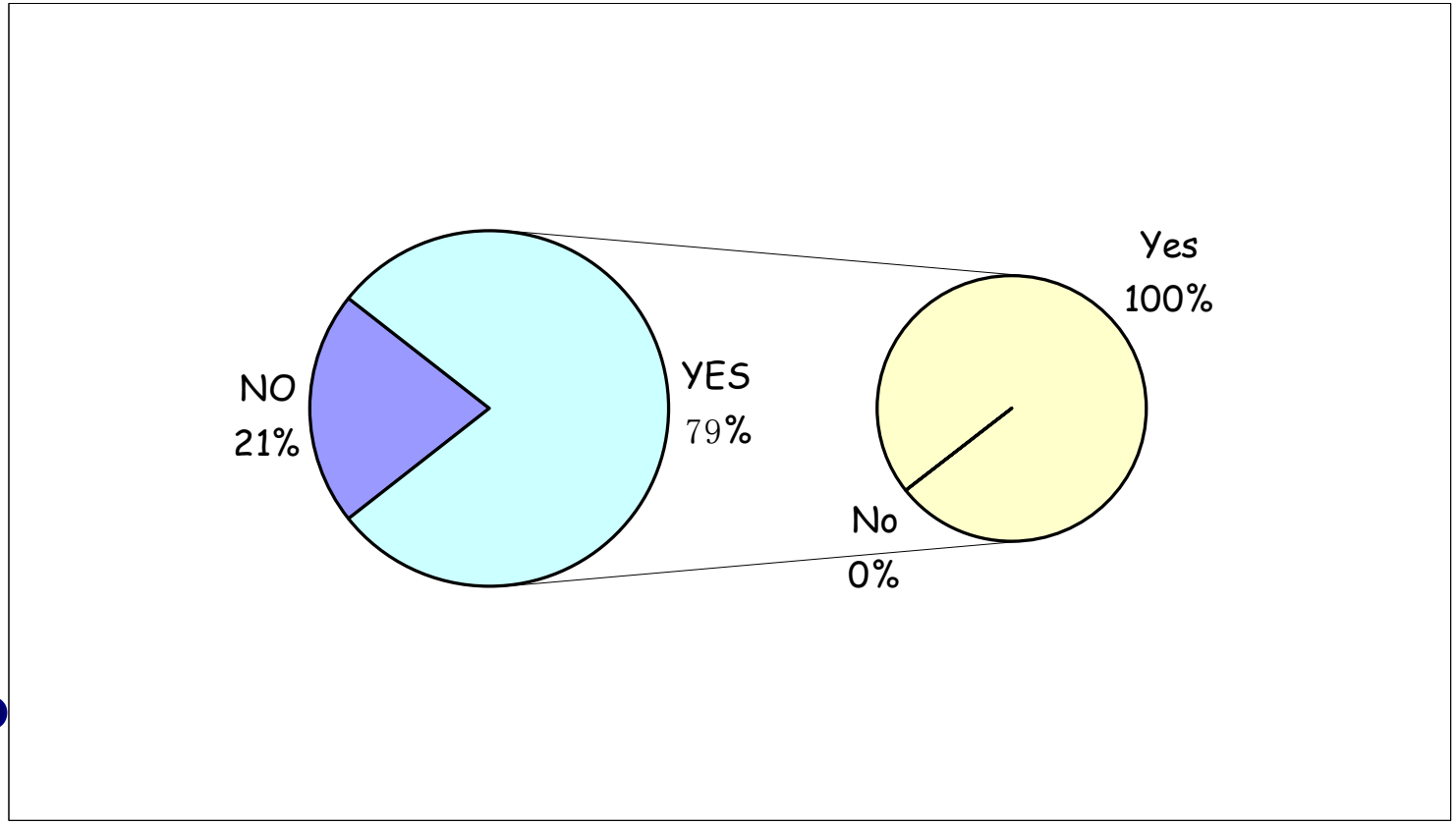
Total	3,014

Sec 2: Pre-market stage

11 members economies have established licensing system,

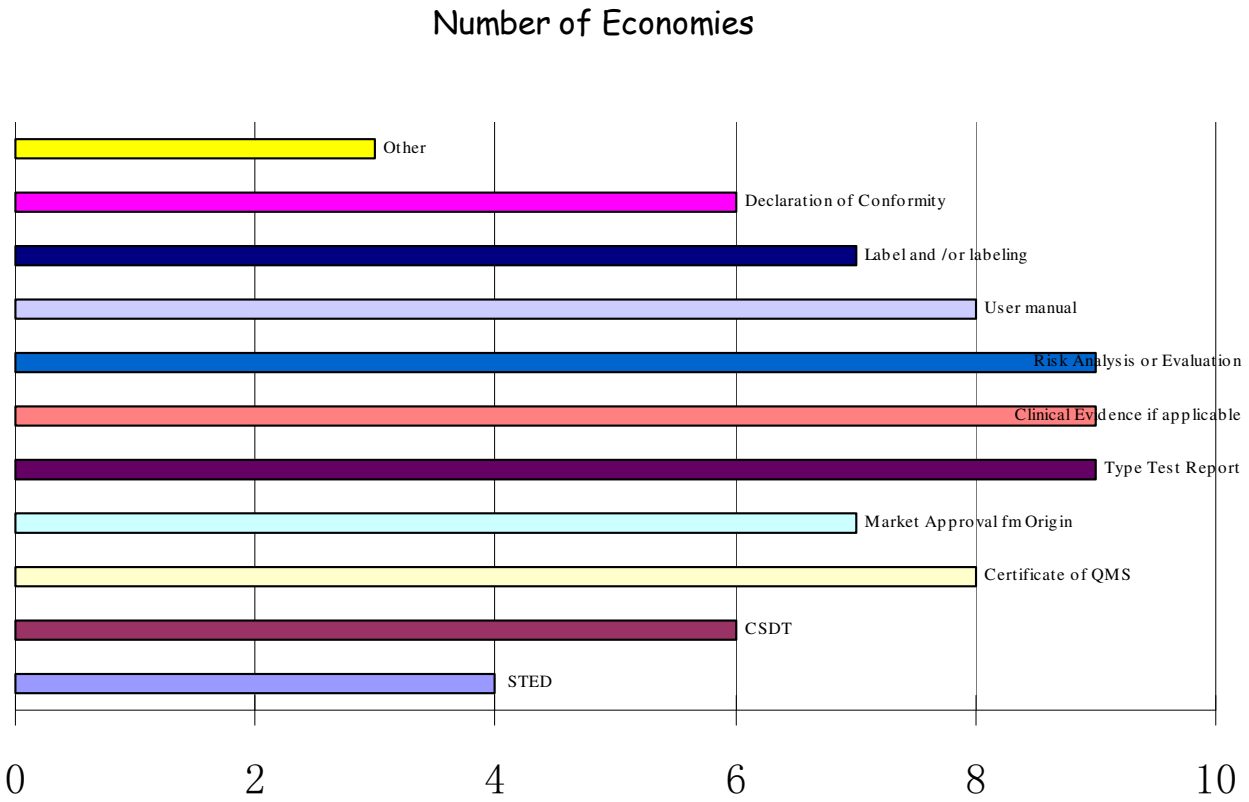
All of them have defined a valid duration of time for license or registration

Q10: Is there a licensing/registration system? Does it have a valid period of time?



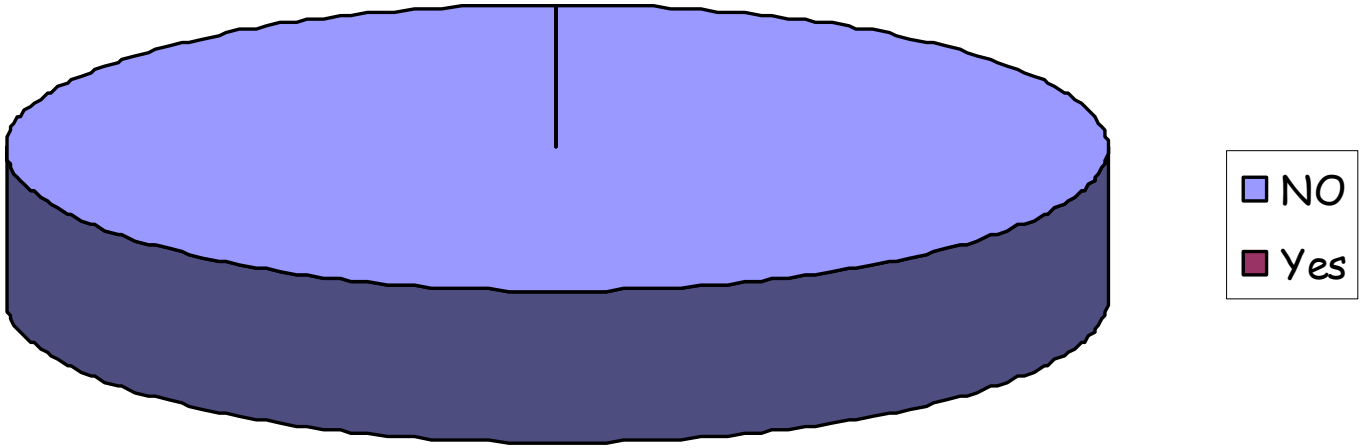
7 member economies have adopted STED or CSDT for submission, 5 members have not; 9 members require documents specially or additionally .

Q12: What other documents (other than STED or CSDT) are required?



So far, there is no member who has a mutual recognition with non-AHWP countries for pre-market approval

Q16: Is there Mutual Recognition Agreement in force between you and non-AHWP country?



Q10-12, 16: Pre-market Approval

No	Member Economies	Is there a licensing system?	Does the license have a valid time?	Is conformity assessment conducted before approval	What document is required for pre-market	MRA with non-AHWP country>
1	Singapore	Yes	Yes	Yes	CSDT	No
2	Saudi Arabia	Yes	Yes	Yes	STED, CSDT	No
3	South Africa	No	-	No	No	No
4	Korea	Yes	Yes	Yes	STED	No
5	China	Yes	Yes	Yes	Other	No
6	Malaysia	No	-	No	No	No
7	India	Yes	Yes	No	CSDT	No
8	Chinese Taipei	Yes	Yes	Yes	Other	No
9	Hong Kong	Yes	Yes	Yes	STED, CSDT	No
10	Thailand	Yes	Yes	Yes	CSDT, Other	No
11	Philippines	Yes	Yes	Yes	Other	No
12	Indonesia	Yes	Yes	Yes	Other	No
13	Vietnam					
14	Myanmar					
15	Cambodia	Yes	Yes	Yes	Other	No
16	Laos	No	-	No	CSDT	No
17	Brunei					

Q12.1: What documents (other than CSDT or STED) are required for pre-market submission?

No	Member Economies	Certificate of QMS	Mkt Approval of Country ofOrigin	Type Test Report	Clinical Evidence	Risk Analysis	Manual/ Labeling	DoC
1	Singapore	-	-	-	-	-	-	-
2		-	-	-	-	-	-	-
3	South Africa	-	-	-	-	-	-	-
4		Yes	No	Yes	Yes	Yes	Yes	Yes
5	China	No	Yes	Yes	Yes	Yes	Yes	No
6		-	-	-	-	-	-	-
7	India	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8		Yes	Yes	Yes	Yes	Yes	Yes	Yes
9	Hong Kong	Yes	No	Yes	Yes	Yes	Yes	Yes
10		Yes	Yes	Yes	Yes	Yes	Yes	Yes
11	Philippines	Yes	Yes	Yes	Yes	Yes	Yes	Yes
12		Yes	Yes	Yes	Yes	Yes	Yes	Yes
13	Vietnam							
14								
15	Cambodia	Yes	Yes	Yes	Yes	Yes	No	No
16		-	-	-	-	-	-	-
17	Brunei							

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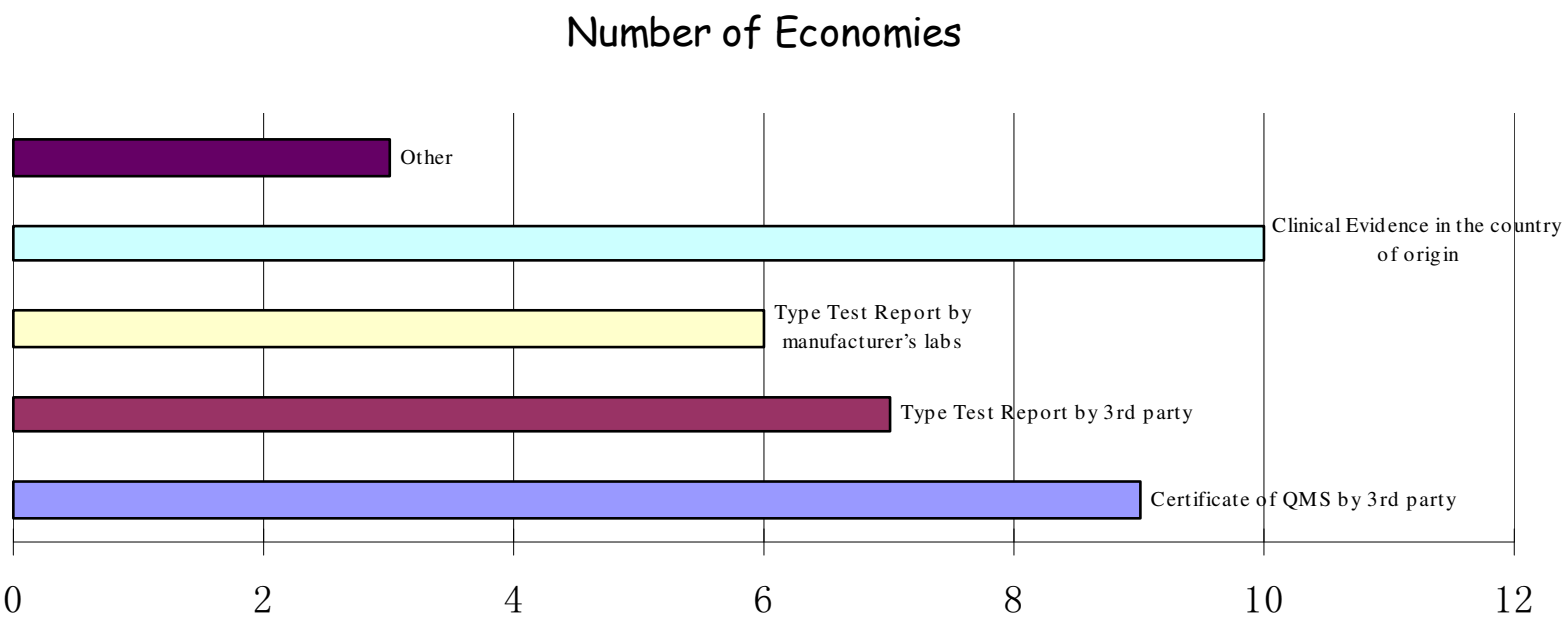
10 member economies accept clinical evidence from country of origin
9 accept certificate of QMS by intl recognized 3rd party
7 accept type test by intl recognized 3rd party
6 accept type test by manufacturer's test lab

Q13: What of the below are acceptable for pre-market submission?

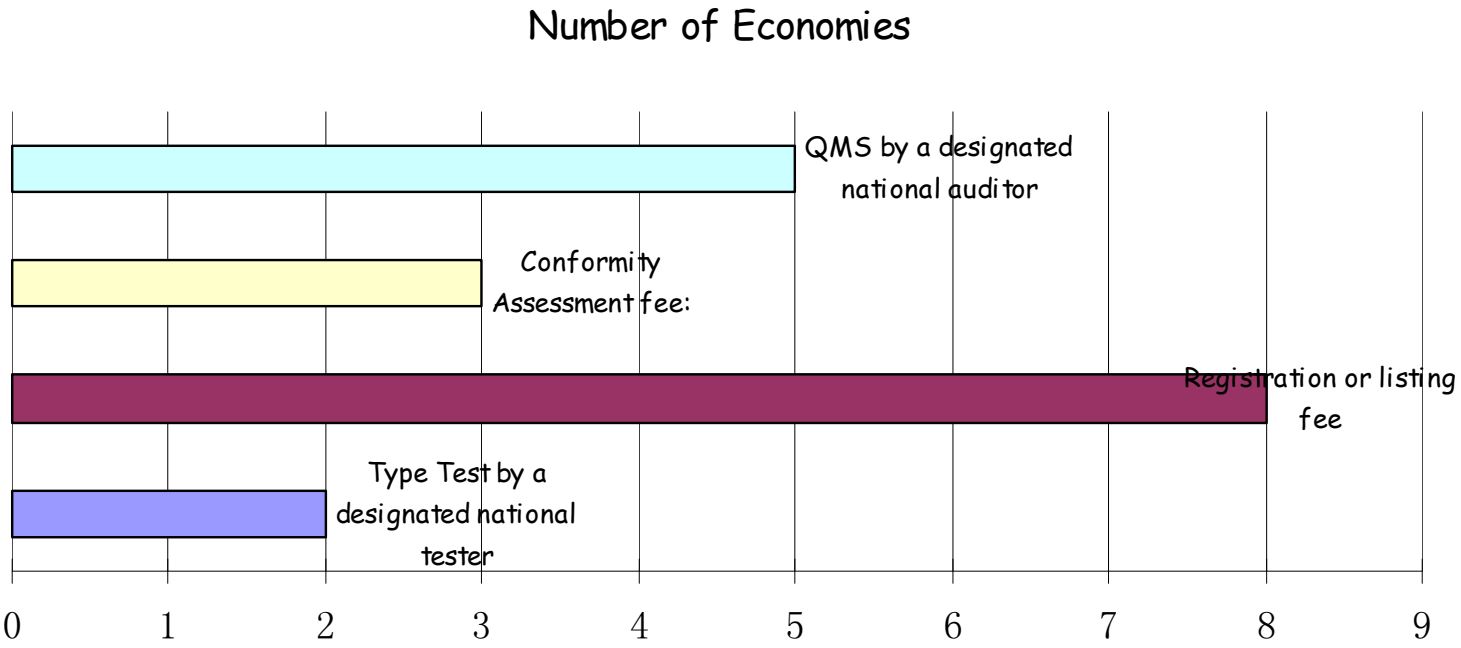


Q13: What documents below are acceptable for pre-market approval?

No	Member Economies	Certificate of QMS of intl 3rd party	Type Test of intl recognized 3rd party	Type Test of manufacturer lab	Clinical Evidence of country of origin
1	Singapore	Yes	Yes	No	Yes
2	Saudi Arabia	Yes	Yes	Yes	Yes
3	South Africa	-	-	-	-
4	Korea	Yes	Yes	Yes	Yes
5	China	No	No	NO	Yes
6	Malaysia	-	-	-	-
7	India	Yes	Yes	Yes	Yes
8	Chinese Taipei	Yes	Yes	Yes	Yes
9	Hong Kong	Yes	No	No	Yes
10	Thailand	Yes	Yes	Yes	Yes
11	Philippines	Yes	Yes	Yes	Yes
12	Indonesia	Yes	Yes	Yes	Yes
13	Vietnam				
14	Myanmar				
15	Cambodia	Yes	No	No	Yes
16	Laos	No	No	No	Yes
17	Brunei				

8 members economies require registration or listing fees,
Only 2 members require mandatory type test by designated national tester

Q14: What of the below are mandatory for pre-market approval?

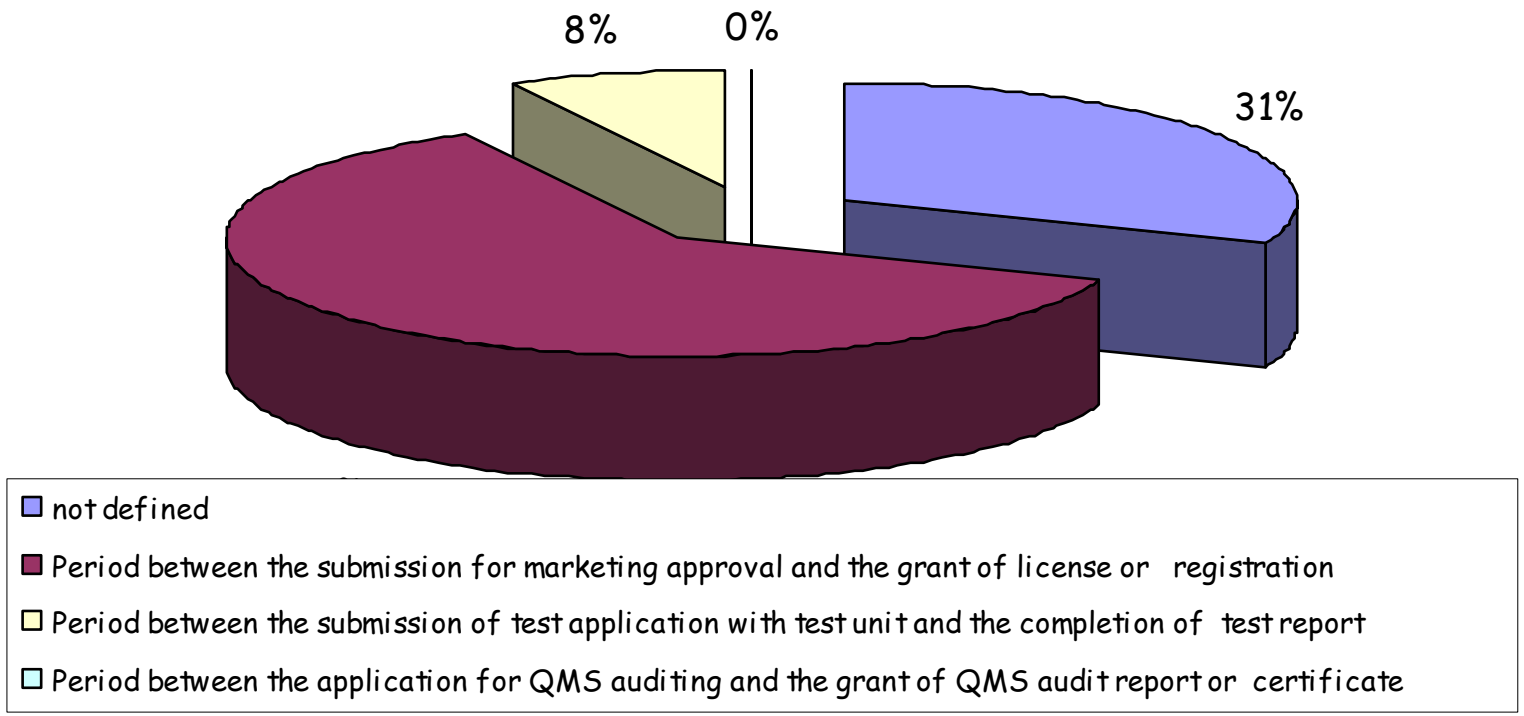


Q14: What documents below are mandatory required for pre-market approval?

No	Member Economies	Type test by designated national tester	Registration/ listing fee	Conformity Assessment fee	QMS by designated national auditor
1	Singapore	No	Yes	No	No
2	Saudi Arabia	No	Yes	Yes	Yes
3	South Africa	-	-	-	-
4	Korea	No	Yes	-	Yes
5	China	Yes	No	No	Yes
6	Malaysia	-	-	-	-
7	India	No	Yes	No	No
8	Chinese Taipei	No	Yes	Yes	Yes
9	Hong Kong	No	No	Yes	Yes
10	Thailand	Yes	Yes	No	No
11	Philippines	No	Yes	No	No
12	Indonesia	No	Yes	No	No
13	Vietnam				
14	Myanmar	Yes	Yes	No	No
15	Cambodia	-	-	-	-
16	Laos				
17	Brunei				

Q15: 8 members economies have defined the timeline for pre -market approval
4 members have no timeline defined by regulation for approval of registration

Q15: Is there a time period of registration defined by regulation?

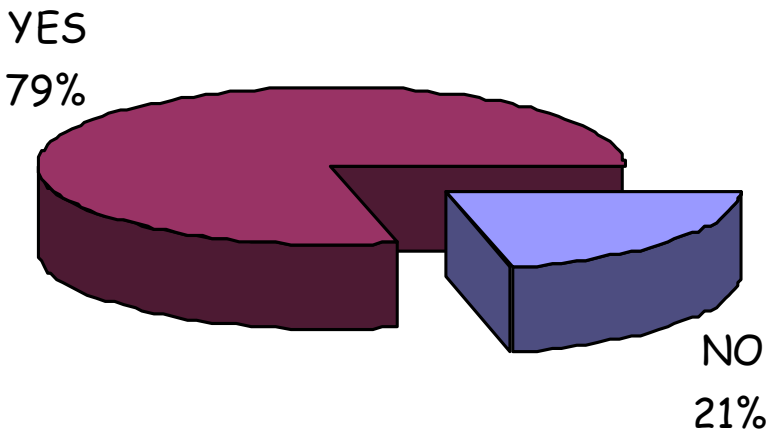


Sec 3: Labeling, Advertising and Distributing

11 member economies have established advertising and labeling requirements,

Only 3 have not

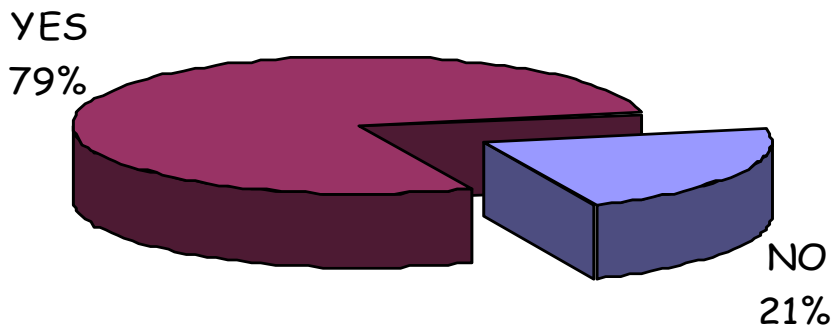
Q17: Is there advertising, labeling requirements for MD?



11 member economies have established licensing requirements for distributors/importers

3 have not

Q19: Is there special regulatory (licensing) requirements for distributors or importers?



Sec 4: Post-market Stage

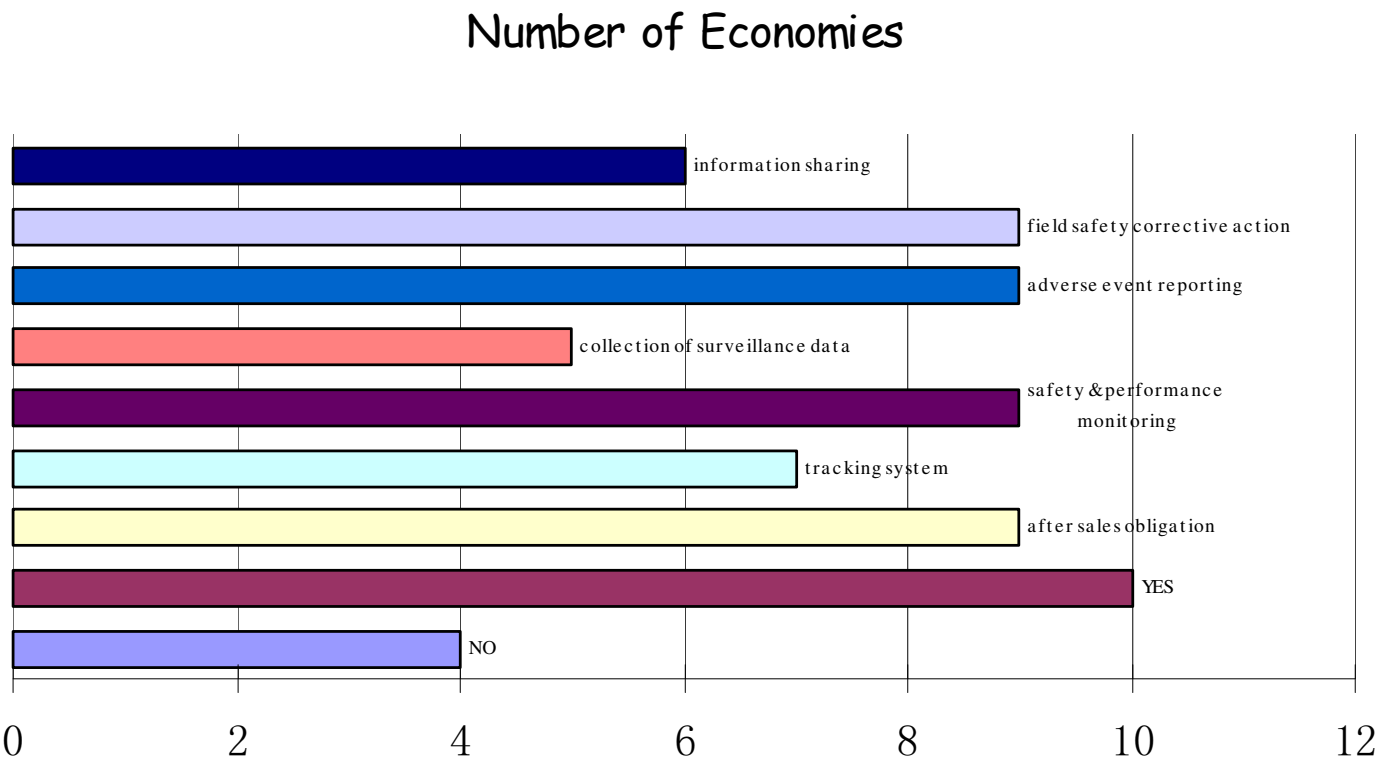
10 member economies have established post-market requirements

9 of them require averse event reporting

6 have applied GHTF guidelines

4 have not established post-market requirements yet

Q20: Are there any regulatory requirements for mfr's post-market surveillance?



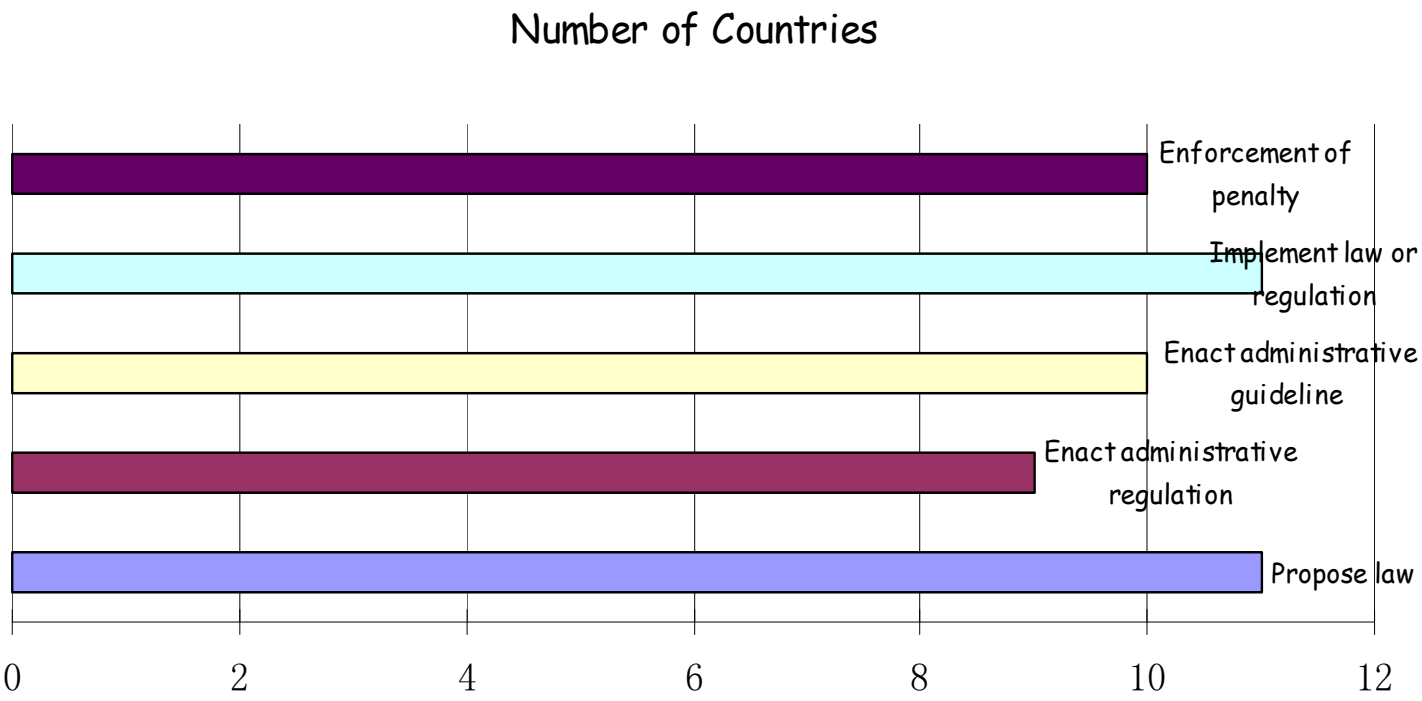
Q20: What below are required for post-market surveillance?

No	Member Economies	After-sale obligation	Tracking system	Safety Monitoring	Data collection	Event Reporting	Field Correction	Info Sharing
1	Singapore	Yes	Yes	Yes	No	Yes	Yes	No
2	Saudi Arabia	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3	South Africa	No	No	No	No	No	No	No
4	Korea	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5	China	Yes	Yes	Yes	Yes	Yes	Yes	No
6	Malaysia	No	No	No	No	No	No	No
7	India	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8	Chinese Taipei	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9	Hong Kong	Yes	Yes	Yes	Yes	Yes	Yes	No
10	Thailand	Yes	No	Yes	Yes	Yes	Yes	Yes
11	Philippines	No	No	No	No	No	No	No
12	Indonesia	Yes	No	Yes	Yes	Yes	Yes	Yes
13	Vietnam	-	-	-	-	-	-	-
14	Myanmar	-	-	-	-	-	-	-
15	Cambodia	No	No	No	NO	No	No	No
16	Laos	No	No	No	No	No	No	Yes
17	Brunei	-	-	-	-	-	-	-

Sec 5: Regulatory Authority

Majority of member economies have the similar power / rights as listed below;
More authorities tend to propose regulation and implement regulation enacted

Q25: What are the powers of regulatory authority?

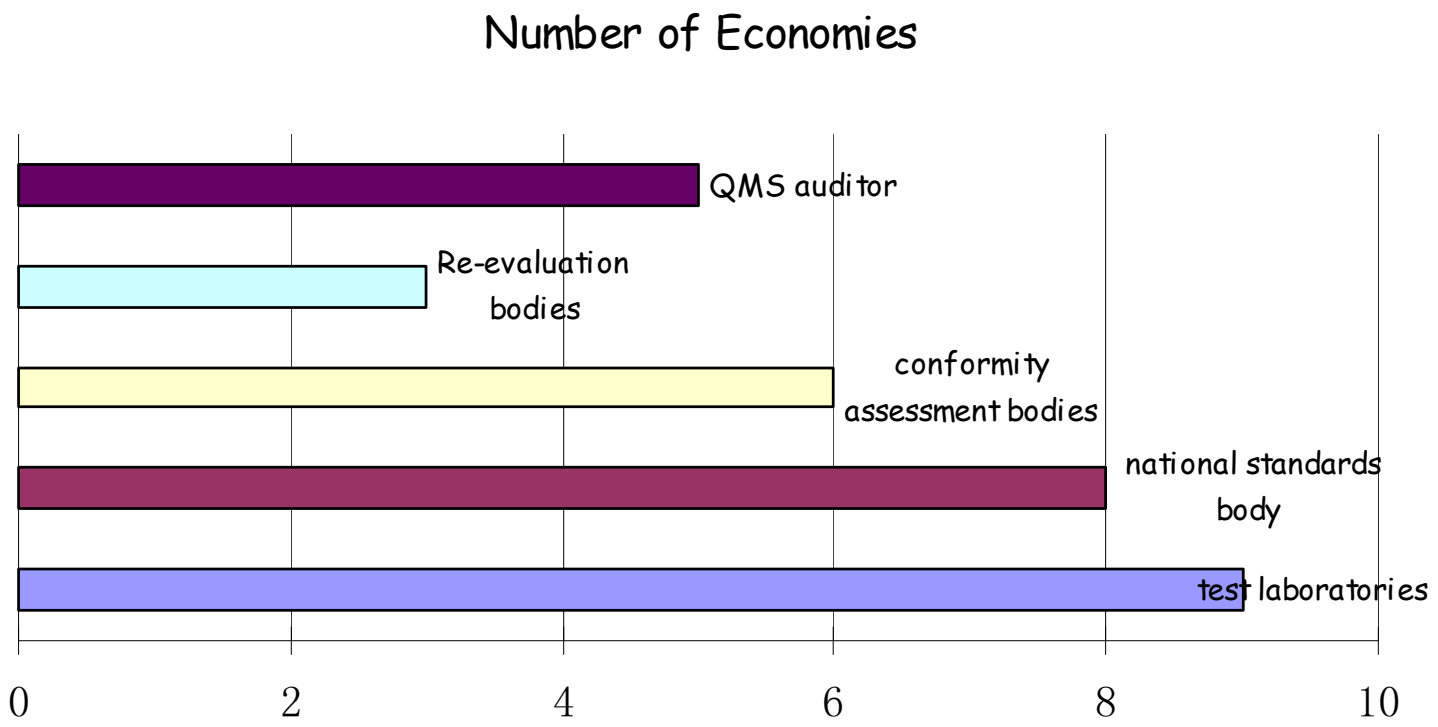


Sec 6: Organizational Development

9 member economies have developed the test institution;

3 members have established re -evaluation body

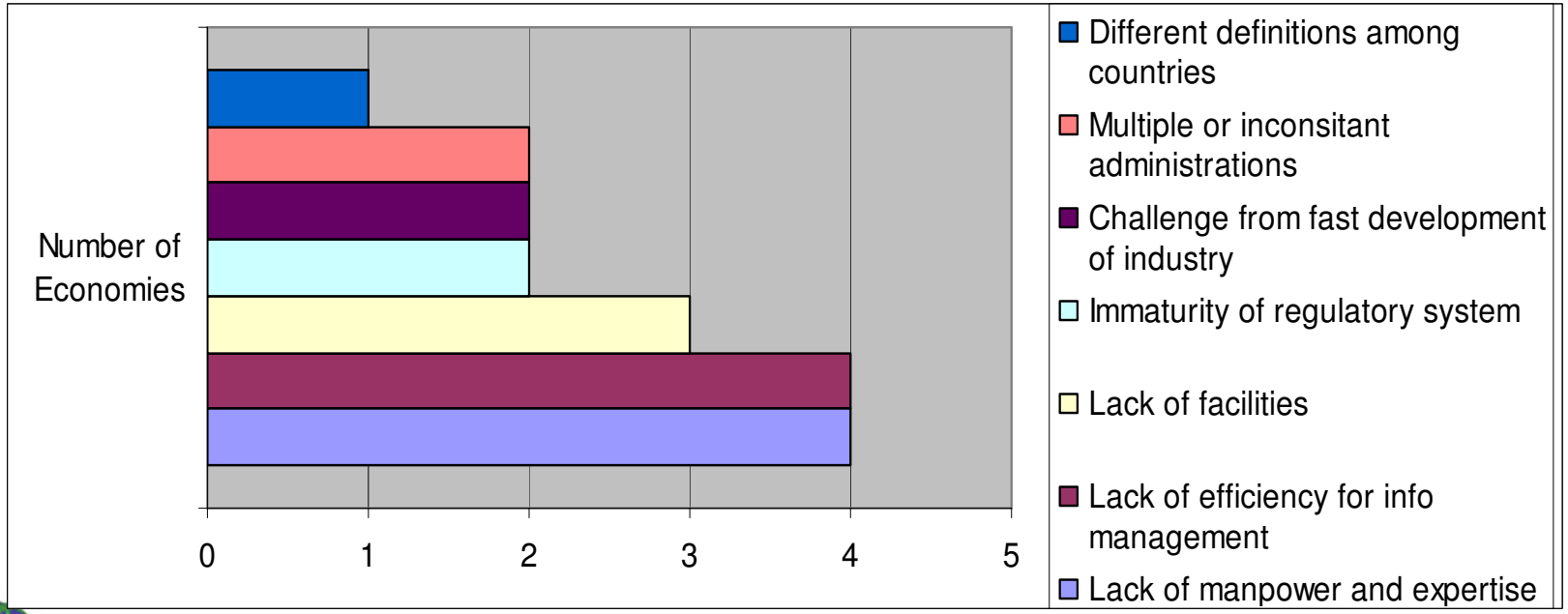
Q 29: What organizations are developed to support implementation of regulatory system?



Sec 6: Organizational Development

4 member economies responded insufficiency of manpower and expertise;
4 responded inefficiency for information exchange & management;
3 insufficient facilities

Q 30: Is there any challenge in regulatory system to facilitate the control of medical devices?



Main findings

1. Response rate is good, some members are still working on and submit later
2. Among 14 responders, 11 have an existing regulatory systems
3. Very many members have already adopted GHTF definitions of MD, manufacturer, classification and essential principles for safety and performance
4. More than half members can accept clinical evidence from mfr's countries
5. Majority of members have setup requirements or licensing system for labeling, advertising or distributing.
6. Although there is still big diversity, the converge have been found as main stream in most of areas.
7. Essential principles of safety and performance are not set up in many members (8).
8. Increasing manpower and expertise, and enhancing information sharing and management are identified as the main challenges in regulatory systems

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Conclusions

• The survey results would be provided to TC WGs who would make more specific recommendations or guidelines in their WG documents

• More analysis and trend analysis will be conducted next time when we accumulate more information year by year.

•It would not be the main intention for this study to identify specific status or legal requirements in specific members among which there are a lot of diversities in social, economical and cultural aspects, but to show AHWP picture as a whole.

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Thank you all who have contributed to this survey?

Special thanks to

- Regulators who filled out the Questionnaire forms and
- industry representatives who helped to coordinate in the survey
- Secretariat members in HK and Mainland China

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