ASEAN Medical Devices Regulatory Harmonization Update

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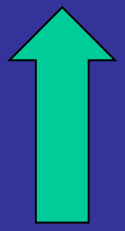
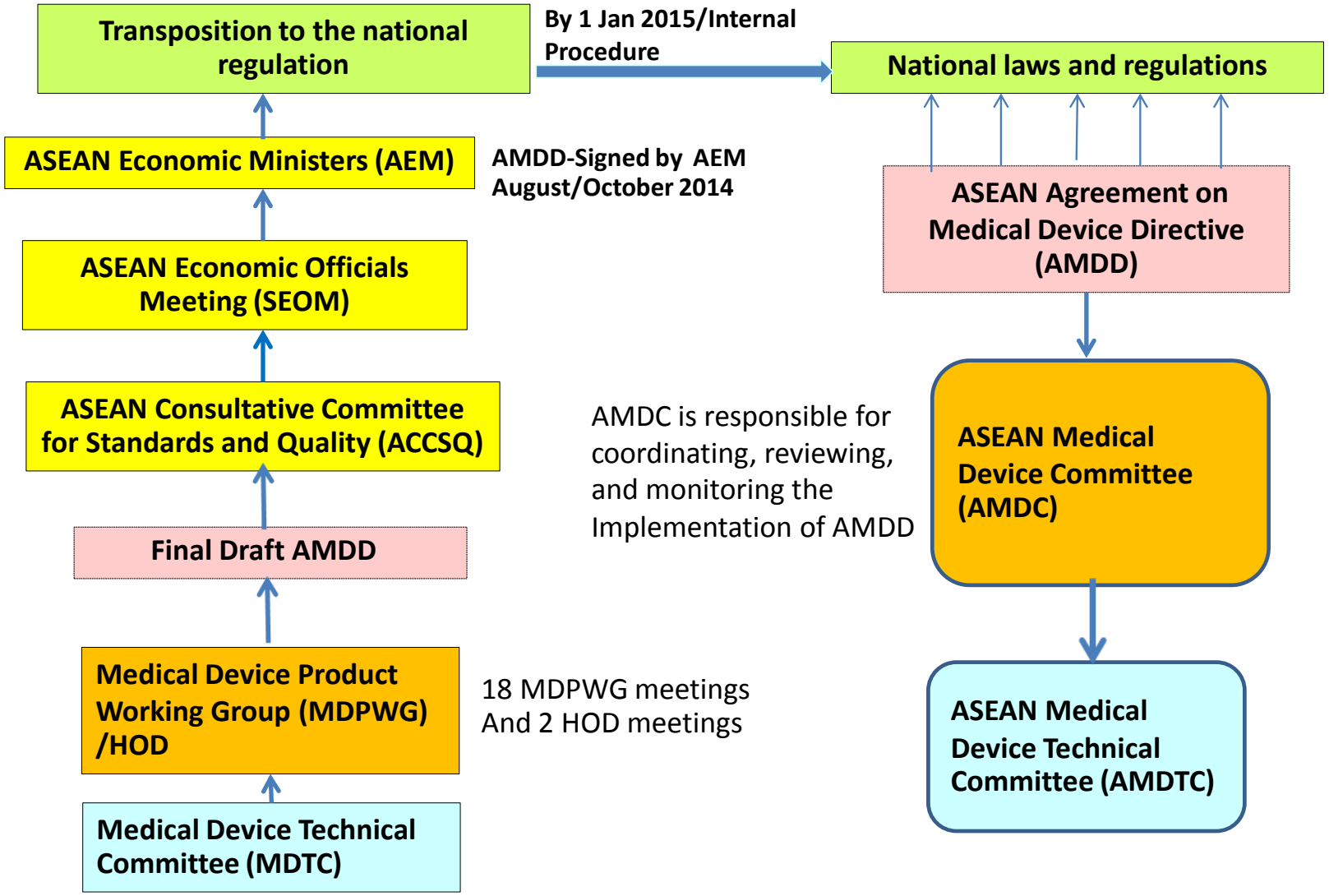
ASEAN Economic Community (AEC) [31 Dec 2015]



ASEAN Agreement on Medical Device Directive: AMDD [1 Jan 2015/Internal Procedure]

ASEAN Medical Device Harmonization

ASEAN Roadmap for Implementation of AMDD



ASEAN Medical Device Market

Population	**620 million**	**10 member countries** - **Brunei** - **Cambodia** - **Indonesia** - **Laos** - **Malaysia** - **Myanmar** - **Philippines** - **Singapore** - **Thailand** - **Vietnam**
GDP	US$ 2.3 trillion in 2012	
Economic growth	5.3% in 2012	
Total value of ASEAN medical device market	> US$ 4.5 billion in 2013	Expected increase to US$ 8 billion by 2017

Contents of AMDD: 24 Articles 8 Annexes

Scope of AMDD: limited to medical device for human use only

Art.1	General Provisions	Art.5	Conformity Assessment of Medical Devices
Art.2	Definitions and Scope	Art.6	Registration and Placement on the Market
Art.3	Essential Principles of Safety and Performance of Medical Device	Art.7	Licensing of Person Responsible for Placing Medical Devices on the Markets of Member States
Art.4	Classification of Medical Devices	Art.8	Technical Documents for Medical Devices
		Art.9	Reference to Technical Standards

Contents of AMDD: 24 Articles 8 Annexes

Scope of AMDD: limited to medical device for human use only

Art.10	Labelling	Art.18	Implementation
Art.11	Medical Device Claims	Art.19	Revisions, Modifications and Amendments
Art.12	Post-Marketing Alert System	Art.20	Dispute Settlement
Art.13	Clinical Investigation	Art.21	Reservations
Art.14	Institutional Arrangements	Art.22	Entry into Force
Art.15	Safeguard Clauses	Art.23	Annexes
Art.16	Confidentiality	Art.24	Depositary
Art.17	Special Cases		

Contents of AMDD: 24 Articles 8 Annexes

Annex1	Essential Principles of Safety and Performance of Medical Devices
Annex2	Risk Classification Rules for Medical Devices other than IVD Medical Devices
Annex3	Risk Classification Rules for IVD Medical Devices
Annex4	ASEAN Common Submission Dossier Template
Annex5	Post Marketing Alert System (PMAS) Requirements
Annex6	Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)
Annex7	Labelling Requirements
Annex8	Clinical Investigation

MEDICAL DEVICE Definition

"medical device" shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

(i) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

MEDICAL DEVICE Definition

(A) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(B) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(C) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(D) supporting or sustaining life;

(E) control of conception;

(F) disinfection of medical devices; and

(G) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the

MEDICAL DEVICE Definition

(ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

IVD Medical Device Definition

"in vitro diagnostic (IVD) medical device" means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information:

IVD Medical Device

(i) concerning a physiological or pathological state or a congenital abnormality;

(ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

(iii) to monitor therapeutic measures; and

includes a specimen receptacle.

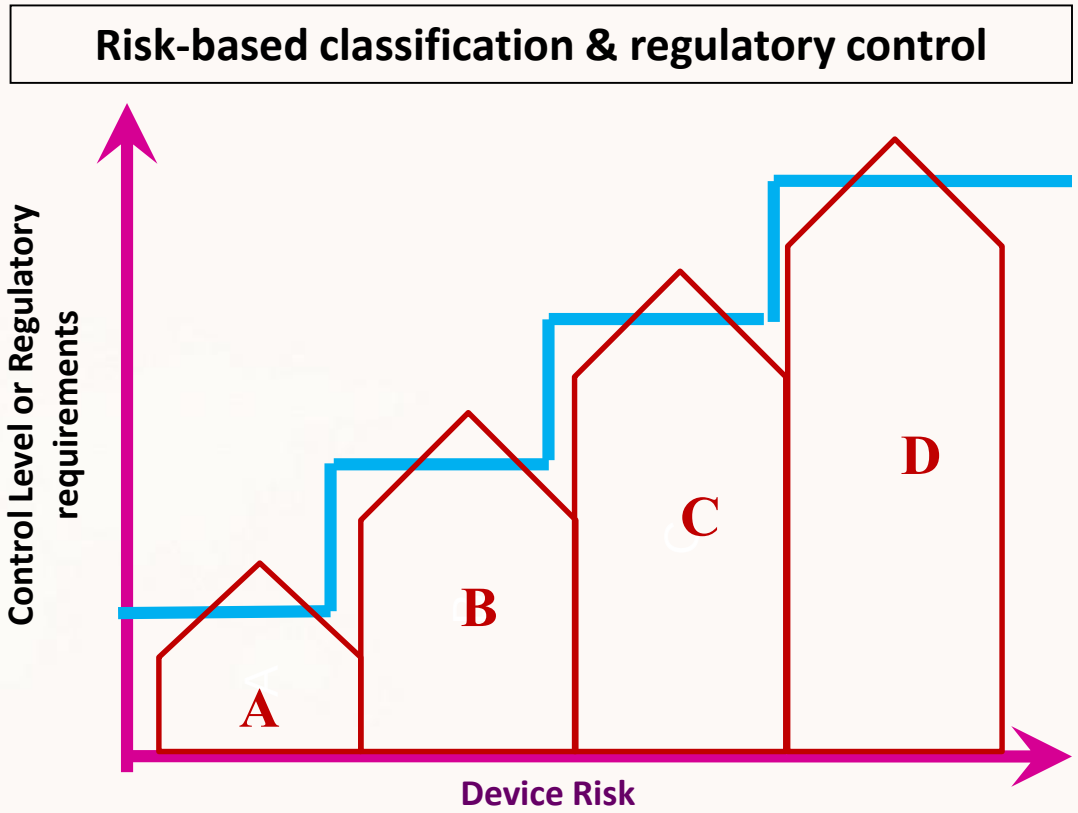
Classification of Medical Devices

- Risk classification rules for medical devices (non IVD) --- 16 rules
- Risk classification rules for IVD medical devices --- 7 rules

Classification of Medical Devices

Annex 2 of AMDD **Non IVD medical devices**	**Annex 3 of AMDD** **IVD medical devices**
(16 Rules) Class A Low risk Class B Low-moderate risk Class C Moderate-high risk Class D High risk	(7 Rules) Class A **Low Individual Risk and Low Public Health Risk** Class B **Moderate Individual Risk and/or Low Public Health Risk** Class C **High Individual Risk and/or Moderate Public Health Risk** Class D **High Individual Risk and High Public Health Risk**

Understood Concept of Control vs Risk



Important measures or system that each member state must put in place or implement :

1. **licensing of person responsible for placing the medical device in that member state or authorized representative**
2. **registration of the product**

→ **Letter of Authorization by product owner**

Registration of Medical Devices

1. The Regulatory Authority of the Member State may exempt certain medical devices from the requirement for registration where appropriate.
2. Custom-made medical devices shall not be subjected to product registration requirements.

3. **Conformity Assessment of Medical Devices by regulatory authority or any appointed bodies recognized by regulatory authority**

4. **Medical devices shall meet the essential principles of safety and performance of medical devices**

Annex 1 Essential Principles of Safety and Performance of Medical Devices -1

- General requirements
- Design and Manufacturing Requirements

- Chemical, physical and biological properties
- Infection and microbial contamination
- Manufacturing and environmental properties
- Medical devices with a diagnostic or measuring function
- Protection against radiation
- Requirements for medical devices connected to or equipped with an energy source

Annex 1 Essential Principles of Safety and Performance of Medical Devices -2

- Protection against mechanical risks
- Protection against the risks posed to the patient by supplied energy or substances
- Active implantable medical devices
- Protection against the risks posed to the patient for medical devices for self-testing or self-administration
- Information supplied by the product owner
- Clinical investigation

5. Use of product registration submission format: Common Submission Dossier template (CSDT)

INTRODUCTION

The Common Submission Dossier Template (CSDT) should reduce the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of the CSDT in ASEAN should minimise the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different Regulatory Authorities.

Common Submission Dossier template (CSDT)

SCOPE

- **The CSDT applies to all medical devices. For IVD medical devices, the Regulatory Authority of the Member State may choose to adopt this CSDT or prescribe another format for regulatory submissions to that Member States.**
- **The depth and detail of the information contained in the CSDT will depend on:**

  - classification of the subject medical device;

  - complexity of the subject medical device.

Common Submission Dossier template (CSDT)

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading.

Common Submission Dossier template (CSDT) -1

I. EXECUTIVE SUMMARY

An executive summary shall be provided with the common submission dossier template, which shall include the following information:

- **an overview, e.g., introductory descriptive information on the medical device, the intended purposes and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT;**
- **commercial marketing history;**
- **intended purposes and indications in labelling;**
- **list of regulatory approval or marketing clearance obtained;**
- **status of any pending request for market clearance; and**
- **important safety/performance related information.**

Common Submission Dossier template (CSDT) - 2

II. ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE

1. Relevant Essential Principles and Method Used to Demonstrate Conformity
2. Medical Device Description
3. Summary of Design Verification and Validation Documents
4. Medical Device Labelling
5. Risk Analysis
6. Physical Manufacturer Information

+ Declaration of conformity by product owner or physical manufacturer

Reference to Technical Standards of Medical devices

(1) Medical devices which conform to either the relevant technical standards recognised by the AMDC or other standards accepted by the Regulatory Authority of a Member State for the medical device to be placed in the market of that Member State shall be deemed to comply with the applicable essential principles referred to in Article 3.

(2) The AMDC may revise by consensus, the recognised technical standards referred to in paragraph 1 of this Article.

6. Post Marketing Alert System (PMAS) Requirements

- **The Regulatory Authorities in the Member States may adopt the recommended post-market alerting system requirements in the Annex 5 or prescribe their own post-market alerting system requirements.**

Annex 5

- **Importation and/or distribution records**
- **Complaint records**
- **Adverse event (AE) reporting criteria and reporting format**
- **Field Safety Corrective Action (FSCA) reporting format**

7. Labelling of medical devices

(1) A medical device shall be labelled in accordance with the requirements of the Member State prior to placing on the market in that Member State.

(2) Member States may set the labelling requirements for a medical device in accordance with Annex 7 or as deemed appropriate by the Member States.

(3) Member States may set the requirement for having the label of a medical device in their national languages.

8. **Clinical Investigation** - Member States shall put in place an appropriate system for the conduct of clinical investigation of medical devices, taking into account the Helsinki Declaration

9. **Medical Device Claim** - Control of medical device claims