VIETNAM MEDICAL DEVICES CONTROLS Updates

Department of Medical Devices and Construction Vietnam MOH
MBA, Bio Eng Doan Quang Minh
On behalf of Mr Nguyen Minh Tuan - Director General

VIETNAM updates

CONTENT

- DECREE 36/2016/NĐ-CP
    - IMPLEMENTATION STAGE
    - KEY ACHIEVEMENTS & CHALLENGES
- DRAFT OF AMENDED DECREE 36
    - HIGHLIGHTS OF CHANGES
- UPDATED STATUS

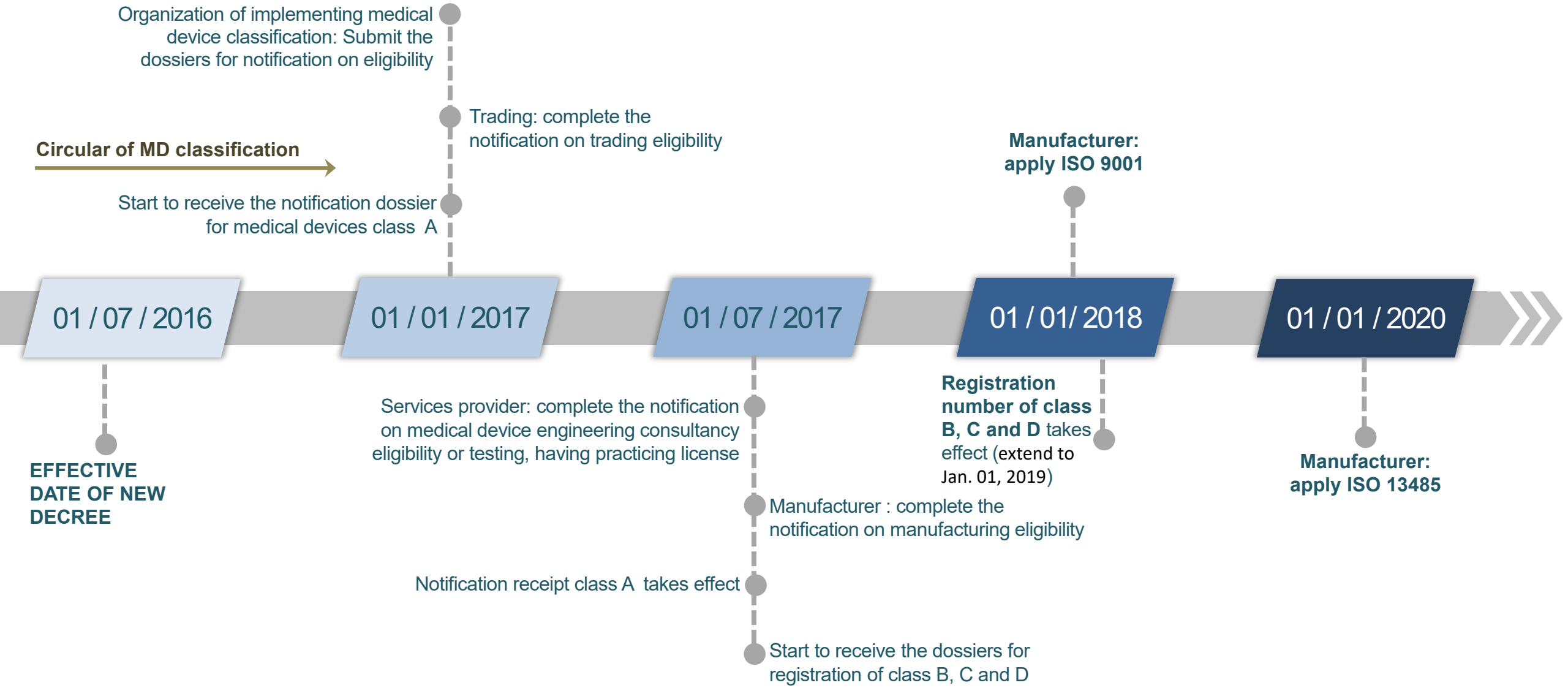
VIETNAM updates

- Vietnam has ratified AMDD in 2016

- has developed Decree 36 on management of medical devices in harmony with the international commitments

REGULATIONS

EFFECTIVE DATES AND IMPLEMENTATION STAGES – DECREE 36



REGULATIONS

REGISTRATION: AUTHORITY APPROVAL AND TIMELINES

Registration	Submitted Timeline	Timeline for approval	Effective of license	License validity	Approved Authority	Registration fee
Class A	From 1 Jan 2017	5 working days	01 Jul 2017	Permanent	DOH	1 Mio VND (~45 USD)
Class B/C/D	From 1 Jul 2017	60 working days	01 Jan 2019	5 years	DMEC	Class B: 3 Mio VND (~135 USD) Class C, D: 5 Mio VND (~225 USD)

Medical Device Classification

Vietnam recognizes classification results from countries: ASEAN, EU, USA, Japan, Korea, Australia and Canada.

It is required to submit the following documents:

a) Free Sale Certificate
b) Marketing Authorization
c) Export license
d) Other documents issued by the foreign authorities, including the classification results claimed in official website

In case THE ABOVE documents ARE NOT AVAILABLE, the classification in Vietnam WILL BE GIVEN BY AN authorized organization.

Reference: Decree 36/2016/ND-CP dated May.15, 2016
Resolution 131/NQ-CP dated December 6, 2017
Dispatch 7165/BYT-TB-CT dated December 14, 2017

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Decree 36 – key achievements

Several circulars were published

- **Classification: Cir 39,42**
- **Guidance for implementation: Cir 46**
- **HS code: Cir 14**

Training workshops

to establish the medical device management system for 63 provinces

01 / 07 / 2016

EFFECTIVE OF NEW DECREE

Coordinate with Other Agencies to develop the necessary guidance

- **Fees: Cir 278**
- **Labelling: Decree 43**
- **Penalty: Decree 176 and amended Decree 176**
- **cut down on business conditions**

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Decree 36 – Challenges

Current Regulations

Submit and follow import license (Cir.30, Cir.47)

STOP

START

New Decree 36

Class B/C/D submission and approval

Reg Number (Class B,C&D) take effect from Jan.01, 2019

1/7/2017

1/1/2019

- **CURRENTLY we have only < 1-2 months before implementation**
- **Approx. 8000 application need to be reviewed and approved**

- Infrastructure for the implementation of class B, C and D registration
- Human Resource
- FULL CSTD application
- Control of IVD device containing drugs
- Post market surveillance

amended Decree 36

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Amended Decree 36 – Key highlights

- Extend - implementation date of class B, C and D for one more year to Jan 01, 2020
- auto-extend import licenses (as per Circular 30) till 31st Dec 2019

- Fast track approval concept

- Harmonization concept
  - ✓ Post market surveillance (AE/FSCA)
  - ✓ Full CSTD application
  - ✓ Manage IVD medical device containing narcotic/ psychotropic

VIETNAM updates

Principles of Medical device regulations management in Vietnam

- Internationally Harmonized
- Commitment for International Cooperation

Thank you for your attention