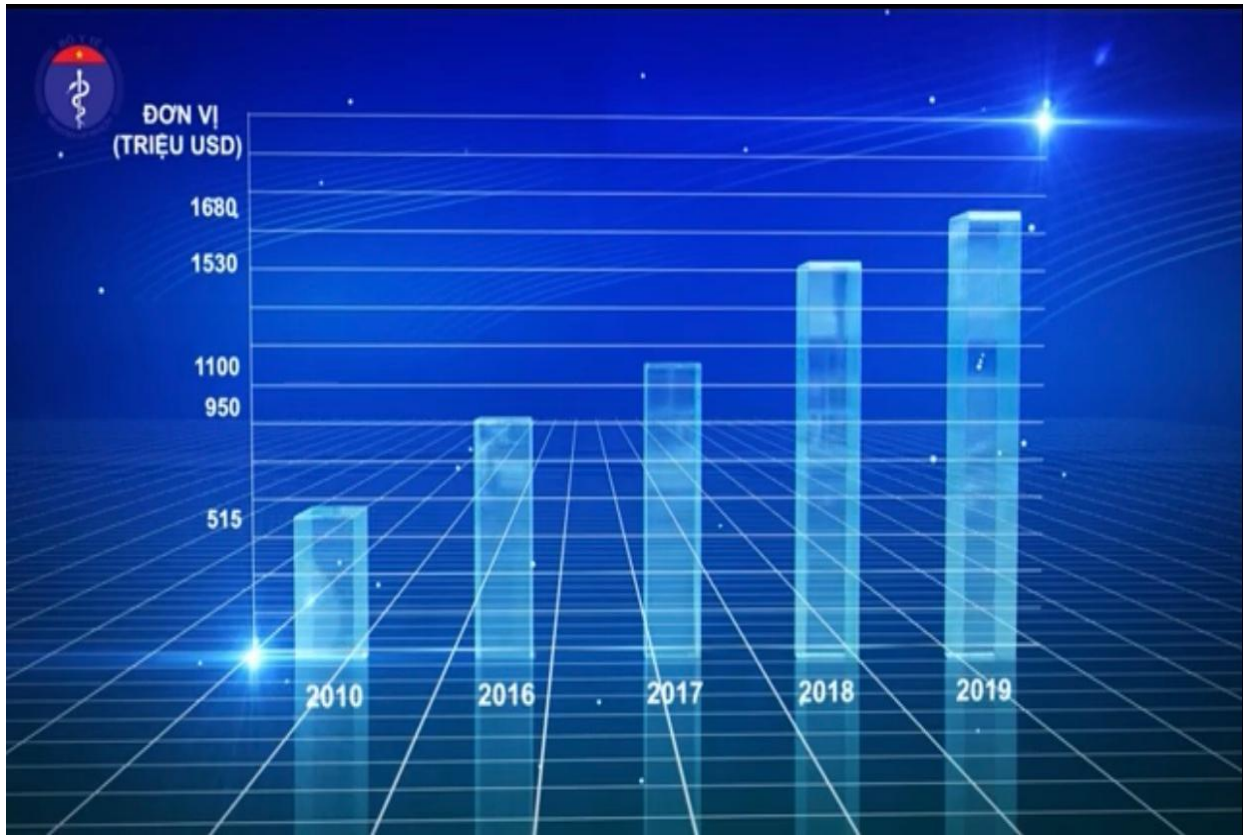
Vietnam Medical Devices Update

Vietnam Ministry of Health – Department of Medical Equipment and Construction

Market Environment

- Vietnam is increasingly integrated into the regional and the world markets.
- The opening up of extensive integration together with efforts to simplify administrative procedures and integration in the field of management → create opportunities to have access to technologies, new and modern curative care methods and medical device → reduce risks and adverse impacts on health and the environment.

Market Environment



- In recent years, the total investment in the medical device market has grown strongly, if the total investment by 2010 was estimated at USD 515 million, in 2016 it was estimated at USD 950 million and reached the estimation of USD 1.1 billion in 2017 and USD 1.680 billion in 2019.

Roadmap for implementation of the Decree on medical device management

Decree 36/2016/ND-CP (issue and effective Jul 1st, 2016)

- All regulations on classification, production and circulation of medical device, management of MD procurement and sale, services, information, labelling, management and use of medical device.
- Regulates the online publicizing and registration, facilitating administrative procedures for businesses operating in the medical device field.
- MoH issued the forms for announcement of eligibility to manufacture, classification, purchase and sale as well as the form of announcement of standards applicable to class A medical device.

Decree 169/2018/ND-CP (issue and effective Dec 31st, 2018)

- Amend and supplement a number of articles of Decree 36/2016/ND-CP to make it more suitable with practical conditions.
- Allowed to automatically renew a number of medical device import permits and circulation permits of class B, C and D.
- Improved and finalized the online procedure system in order to proceed with administrative procedures more smoothly.

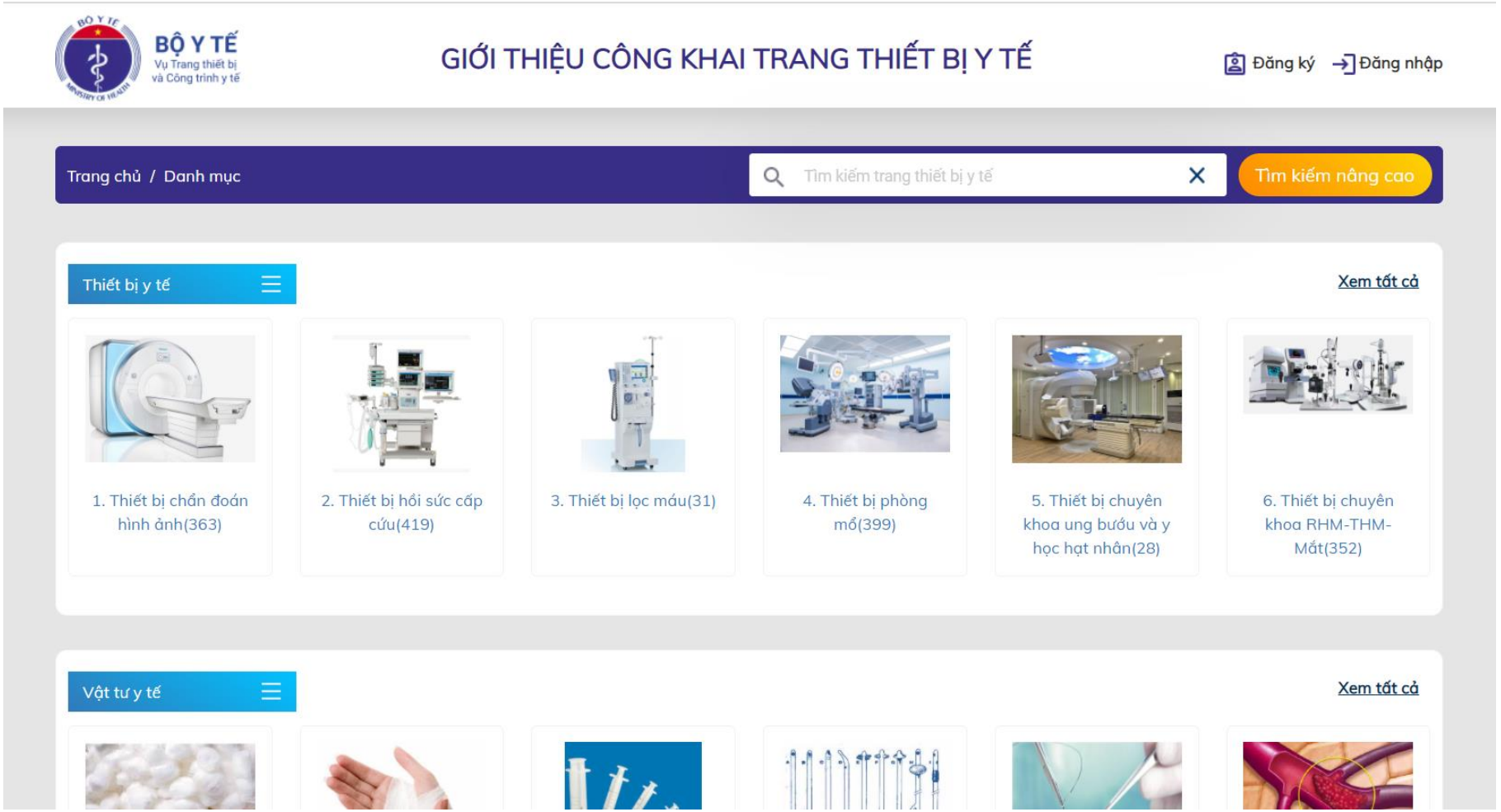
Decree 03/2020/ND-CP (issue and effective Jan 1st, 2020)

- Specifies the validity of licenses for a number of groups of medical device.
- Stipulates the roadmap to apply the ASEAN Common Submission Dossier Template (CSDT) from January 1st, 2022.
- DMEC set up an electronic information portal (in Vietnamese) to manage MD (announcement of eligibility for production and sale; announcement of class A medical device; registration circulation for class B, C, D medical device; issuance of import permits in special cases...) and publicize prices of medical device (https://dmec.moh.gov.vn/).

MoH is draft a new decree to cut down business condition that help to facilitate industry.

Price disclosure

- Publicize prices of medical device for all general medical devices & IVD from Oct 2020 on website https://dmec.moh.gov.vn/
- Number of general medical devices and IVDs that have available price on website: 27.000



License fees

- Along with the implementation process of Decree 36/2016/ND-CP, the Ministry of Health has reviewed the fee rates and adjusted them in accordance with the new regulations.
- MoH coordinates with the Ministry of Finance to promulgate Circular 278/2016/TT-BYT regulating the fee rates, collection and payment modes, management and use of fees in the health sector.
- The Circular stipulates different fee rates for appraisal and issuance of circulation certificates (in which different fees are set for class A, B, C and D medical device according to the principle that examination fee will be higher for dossiers of medical devices with a higher level of risk), appraisal for extension; re-appraisal and re-issuance of import and export permits; assessment of business conditions related to medical device field.

Labelling according to new rules

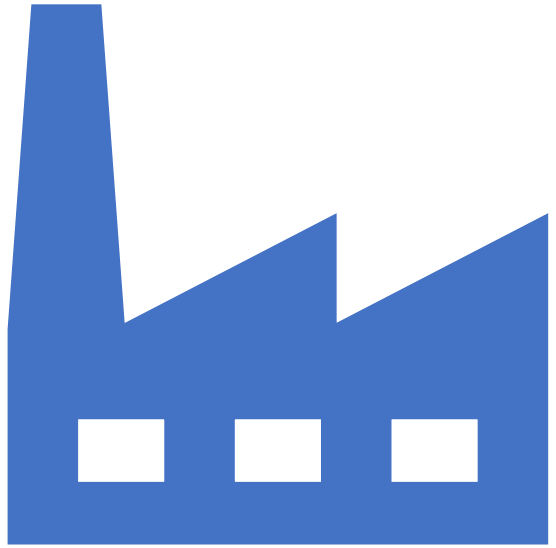
- **Mandatory information on label:**
  - ✓ MoH has reviewed the mandatory contents required for medical device and included them in the Decree on goods labelling (Government Decree No. 43/2017/ND-CP dated April 14, 2017).
  - ✓ In addition to the mandatory information required on the label like all other goods (including name, responsible organization, origin), the MD label should contain other information (circulation number or import permit number, batch or serial number, manufacture date or expiry date, warnings, instructions for use, instructions for storage).
- **Instructions for use in Vietnamese:** is the condition for the medical device to be allowed to circulate on the market.
- **Advertisement:** The MoH issued Circular No. 09/2015/TT-BYT dated May 25th, 2015, stipulating requirements on advertisement content accuracy for special products, goods and services under its management.

Technical requirements for raw materials

- The Decree includes requirements for material dossiers. For reagents, calibrators, in-vitro control materials, material documentation is a mandatory component of the circulation registration application.
- For class B, C, D medical device, according to the roadmap to January 1, 2022, the ASEAN Common Submission Dossier Template (CSDT) will be applied in which the material documentation is also a required component.
- The current Decree also contains special provisions for the import and export of medical device and materials for production of medical device containing drugs and precursors.

Domestic production

- The Decree specifies the conditions for personnel, infrastructure and equipment required for medical device manufacturing facilities.
- Regulates the quality management system of these facilities. They should have a quality management system that meets ISO 13485 before January 1, 2020. They should also declare eligibility to manufacturing medical device prior to manufacturing.
- The Government also has preferential policies for the production of medical device to encourage the development of domestically produced medical device.



Clinical trial evaluation

- Requires in the registration dossier a summary of clinical data and results of clinical trial for class C and D medical device which infiltrate the human body, except for the followings:
  - ✓ medical device which is manufactured or processed in Viet Nam solely for the purpose of export but the importing country does not require clinical trial;
  - ✓ medical device which have been circulated and granted certificate for free sale by one of the countries or organizations, i.e. EU member states (including UK, Switzerland), Japan, Canada , TGA of Australia, FDA of America.
- The Ministry of Health is also drafting a general regulation on clinical trial of medical device, including:
  - ✓ contents of different appraisal stages
  - ✓ appraisal of medical device for circulation
  - ✓ medical device subject to appraisal
  - ✓ medical device fully or partially exempted from evaluation stages
  - ✓ requirements for establishments eligible for appraisal
  - ✓ required dossiers and procedures for appraisal