CHAPTER 16 **MEDICAL DEVICES AND DIAGNOSTICS**

OVERVIEW

The World Health Organisation (WHO) has consistently highlighted the significance of medical equipment in diverse medical interventions, ranging from minor injuries like sprains to more intricate procedures such as HIV/AIDS testing and organ transplantation. Medical equipment plays a pivotal role in patient care across numerous medical fields, encompassing intensive and grassroots medicine, primary healthcare, preventive measures, diagnostics, both acute and chronic treatment, palliative assistance, functional rehabilitation, and medical research. Consequently, medical equipment, along with medications and physicians, stands as one of the triad foundational elements in healthcare.

Medical Devices and Diagnostics Sector Committee was established in May 2016, acting as the representative of the global medical devices and in-vitro diagnostics industry. For over seven years, our objective has been to proactively engage with government bodies, regulatory agencies, payers, healthcare providers, and other relevant stakeholders to champion optimal practices, maintain the utmost industry criteria, and participate in the formulation of healthcare policies in Vietnam. In essence, our aim is to guarantee prompt availability of enduring, cutting-edge, and superior healthcare for every Vietnamese individual. Throughout our endeavours, we are honoured to have forged robust alliances, notably with the Ministry of Health (MOH), on various initiatives that resonate with our shared mission.

I. ACCELERATING THE MARKETING AUTHORISATION PROCESS FOR CLASS C AND D MEDICAL DEVICES

Relevant authorities: Office of Government (OOG), Ministry of Health (MOH)

Issue description

Decree 07[1] has prolonged the import license and marketing authorisation's expiration date to 31 December 2024. This extension allows the MOH more leeway to evaluate and issue marketing authorisation numbers for Class C and D medical devices as per Decree 98[2]. However, the rate of approval for these devices remains noticeably low. Consequently, there is a significant backlog for Class C and D medical device dossiers. From September 2022 until now, 4,297 applications have been processed (including 2,374 applications that have been issued and are still valid; 04 applications have been withdrawn; 01 application has been refused to be appraised; 1,918 applications have been cancelled due to overdue or overdue additions or units registered for cancellation); Appraised with additional requirements: 4,417 applications; Under appraisal: 3,305 applications. At the same time, because there are no regulations on prioritizing processing for advanced medical equipment, systems and technologies, it must be reviewed after for previously submitted applications.[3]

Potential gains/concerns for Vietnam

Several factors contribute to this delay, such as recent upheavals in the healthcare sectors, including manpower shortage, inadequate legal frameworks, and challenges in adapting to the swiftly changing medical trends. This situation sparks concerns over possible supply chain interruptions if these medical devices are not approved by 1 January 2025.

Currently, Decree 98 and Decree 07 lack a distinct procedure for evaluating and issuing marketing authorisation

1 Decree 07/2023/ND-CP dated 03 March 2023 of the Government on amending and supplementing some Articles of Decree 98/2021/ND-CP dated 08 November 2021 of the Government on Medical equipment management (Decree 07).
2 Decree 98/2021/ND-CP dated 08 November 2021 of the Government on Medical equipment management (Decree 98).
3 Letter no. 722/HTTB-DKKD dated 21 December from Infrastructure and Medical Device Administration to the Drug Administration of Vietnam 2023 on responding to EuroCham's recommendations in 2024 Whitebook.

numbers for new Class C and D devices.[4] This absence results in the delayed introduction of new technologies and new medical technologies and methods, restricting Vietnamese citizen's access to ground-breaking diagnosis and treatment options.

In addition, Decree 98 and Decree 07 do not have a mechanism to prioritize the assessment and issuance of marketing authorisation numbers for class C and D medical devices that have been granted import licenses or valid marketing authorisation numbers but have changes resulting in the submission of new marketing authorisation dossiers. This leads to the risk of not being able to continue importing and supplying these medical devices because existing licenses cannot be used.

Recommendations

We would like to make the following recommendations:

- Expedite the evaluation and authorisation processes for Class C and D medical devices to ensure uninterrupted availability and access to essential medical devices;
- Accelerating the issuance of marketing authorisations and crafting a dedicated procedure for new Class C and D medical devices will guarantee a steady provision of innovative and crucial medical devices, fostering sustainable care for the Vietnamese patients; and
- MOH should have a priority mechanism to issue marketing authorisation for products with valid import license/ marketing authorisation but have changes that lead to a new marketing authorisation submission required.

II. THE TENDER OF MEDICAL DEVICES

Relevant authorities: Office of the Government (OOG), Ministry of Health (MOH), Ministry of Finance (MOF), Ministry of Planning and Investment (MPI), and Vietnam Social Security (VSS)

Issue description

The Vietnam National Assembly passed the amended Law on Tender [5] on 23 June 2023 and formally enacted it on 10 July 2023. Set to come into effect on 1 January 2024, this law now recognises six models: instrument placement, cost per test, combined equipment and consumable procurement, equipment-only procurement, consumable-only procurement and outsourced lab services.

Potential gains/concerns for Vietnam

While this is a positive step, for a transparent and efficient bidding process, there is a pressing need to develop new decrees and guiding circulars. This would foster a more accessible and effective bidding system that serves all stakeholders involved.

Recommendations

We would like to make the following recommendations:

- Provide explicit guidelines on bidding procedures for medical devices, especially the cost per test model;
- MDDSC will accompanied with the MOH to organise workshop or training sessions to relevant parties to facilitate seamless implementation.

4 Article 4 of Decree 98/2021/ND-CP dated 08 November 2021 of the Government on Prescribing medical device management. Specifically, medical devices shall be classified into the following 4 classes according to their levels of potential risks related to their designs and manufacture: Class A: Low risk, Class B: Low-moderate risk, Class C: Moderate-high risk, and Class D: High risk.

5 Law 22/2023/QH15 dated 23 June 2023 of the National Assembly of Vietnam on Tender (Law on Tender).

III. SUPPLEMENTARY HEALTH INSURANCE AND HEALTH INSURANCE FUND/BUDGET FOR PREVENTION & PRIMARY HEALTH TO REDUCE THE BURDEN OF TREATMENT

Relevant authorities: Ministry of Health (MOH), Vietnam Social Security (VSS)

Issue description

Vietnamese healthcare system constantly seeks advancements aligned with global and regional best practices, adopting novel techniques to benefit patient diagnosis and treatment. However, some emerging medical devices, services and technology have not been updated/ listed in the existing reimbursement regulations due to their age (4-6 years old). This lack of regular updates can restrict Vietnamese patients from accessing state-of-the-art medical devices, services and technology.

Potential gains/concerns for Vietnam

Addressing this disparity is crucial to offer thorough healthcare coverage. Emphasis should be on extending insurance coverage for early diagnostic procedures, given their potential to drastically improve health outcomes.

Recommendations

- To ensure that Vietnamese patients can have access to new medical devices, services, and technology, we respectfully propose that the MOH speedily updates technical services/ medical devices list in the following circulars and release them:
  - Circular 04[6] on promulgating the schedule, rates and conditions of payment of costs of covered medical supplies to health insurance participants.
  - Circular 43[7] on providing for technical and professional levels in the network of health facilities and Circular 21[8].
  - Circular 22[9] replaced Circular 39[10] promulgated from 2018 on unifying prices of medical examination and treatment services covered by medical insurance among hospitals of the same class across the country and guidelines for applying prices and payment for medical services in certain cases and Circular 13[11].
- Regularly update the list of Medical Technical Services and collaborate with Departments under MOH and Vietnam Social Security to complete the calculation of costs for these services and allow deployment at healthcare facilities nationwide; and
- Given that the Law on Health Insurance is under revision, we also respectfully request National Assembly to endorse reimbursement for early diagnostics, and screening of certain diseases, such as: cervical and breast cancer, and chronic diseases such as diabetic, high blood pressure. This can significantly reduce treatment burdens later on.

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EuroCham Medical Devices and Diagnostics Sector Committee

6 Circular 04/2017/TT/BYT dated 14 April 2017 of Ministry of Health on promulgating the schedule, rates and conditions of payment of costs of covered medical supplies to health insurance participants (Circular 04).

7 Circular 43/2013/TT-BYT dated 11 December 2013 of Ministry of Health on providing for technical and professional levels in the network of health facilities (Circular 43).

8 Circular 21/2017/TT-BYT dated 10 May 2017 of Ministry of Health on amending and complementing the Circular 43/2013/TT-BYT on providing for technical and professional levels in the network of health facilities (Circular 21).

9 Circular 22/2023/TT-BYT dated 17 November 2023 of Ministry of Health on unifying prices of medical examination and treatment services covered by medical insurance among hospitals of the same class across the country and guidelines for applying prices and payment for medical services in certain cases (Circular 22).

10 Circular 39/2018/TT-BYT dated 30 November 2018 of Ministry of Health on unifying prices of medical examination and treatment services covered by medical insurance among hospitals of the same class across the country and guidelines for applying prices and payment for medical services in certain cases (Circular 39).

11 Circular 13/2019/TT-BYT dated 05 July 2019 of Ministry of Health on amending the Circular 39/2018/TT-BYT on unifying prices of medical examination and treatment services covered by medical insurance among hospitals of the same class across the country and guidelines for applying prices and payment for medical services in certain cases (Circular 13).