CHAPTER 15B **MEDICAL DEVICES AND DIAGNOSTICS**

OVERVIEW

Vietnam's healthcare infrastructure has developed rapidly over the past few years. This is thanks to the significant efforts of the Vietnamese authorities to improve public infrastructure across the country and to open the market to private healthcare providers. The related double-digit growth of the Medical Devices and Diagnostics market, which consists of around 90 percent imports, has stimulated Multi-National Companies (MNCs) to better serve the market through investments in a solid local network of partners. This has involved the establishment of representative offices or, very often, the creation of local Vietnamese branches employing and training highly-qualified Vietnamese experts. It has also created opportunities for some MNCs to establish local production.

This has enabled substantial improvements in the access to innovations and knowledge for the Vietnamese healthcare community, as well as an increase in pre-sales and post-sales service levels to healthcare providers, for the benefit of Vietnamese patients. Decree 36[1], which has been largely aligned to international standards, is a significant milestone for the improvement of the regulatory landscape. Its consistent implementation will foster a more efficient and quality-oriented supply of medical devices and diagnostics solutions in Vietnam.

However, a number of issues still need to be addressed in order to keep on the path to a state-of-the-art healthcare system, giving efficient access to innovative and high-quality healthcare to all citizens. The EuroCham Medical Devices and Diagnostics Sector Committee (MDD SC)[2] has identified several key areas of improvement which it would like to address with the authorities, such as:

- Improving regulations on management of medical devices and diagnostics;
- Improving 'not-new' device management, or so called "re-manufactured products;
- Improving regulatory, budgetary and administrative frameworks to optimise usage, quality and costs of medical devices throughout their life cycle;
- Increasing efficiency in post-marketing surveillance and quality management systems to ensure product and service safety;
- Improving the legal framework and accelerating customs processes for importing medical devices;
- Preventing counterfeiting and illegitimate imports;
- Controlling enablement of pre-licensing promotion and marketing or sale registration;
- Increasing transparency, ensuring a level playing field and fair competition in public procurement of medical devices and diagnostics;
- Focusing more on 'homecare' to foster efficiency in the healthcare system;
- Improving awareness and control on utilisation of single-use devices, and;
- Giving a better access to wound care innovations through a clear reimbursement system.

The following sections focus on several of these issues. We remain available for further dialogue and cooperation with Ministry of Health (MOH) and relevant authorities.

1 Decree 36/2016/ND-CP dated 15 May 2016 of the Government on medical device management.

2 Established from 1 April, 2016 under EuroCham's HealthCare Forum. EuroCham's Healthcare Forum is a coordination platform for Sector Committees operating in the Healthcare industry– at present International Quality Medicines – Generic & Biosimilars (IQMED Generic and Biosimilar), Medical Devices and Diagnostics (MDD SC) and Pharmaceuticals (Pharma Group). The Healthcare Forum enables industry representatives to discuss, share and advocate on common interests and topics. Given its inherently diverse nature, it also covers different interests of those industry representatives. All Sector Committees are equally supported by EuroCham.

I. INCONSISTENT IMPLEMENTATION OF REGULATIONS ON VALUE-ADDED TAX FOR IMPORTED MEDICAL DEVICES

Relevant authorities: Ministry of Finance (MOF), General Department of Vietnam Customs (GDC), General Department of Taxation (GDT), Ministry of Health (MOH)

Imported medical devices play an important role in Vietnam's health sector. In 2016, investments in medical devices in Vietnam totalled US$ 950 million. In 2017, this figure increased to US$ 1.1 billion. The growth of investment in medical devices has averaged 18 percent a year for the last 5 years.[3] In particular, 90 percent of medical devices have been imported from foreign countries to meet medical examination and treatment needs of hospitals, of which public hospitals account for 70 percent of the market share.[4]

Therefore, it is possible to see the importance of imported medical devices to Vietnam's health sector. However, recently, the import of medical devices has encountered a number of barriers related to policy implementation, which has had a considerable impact on the operation of the sector. Those include the inconsistent implementation of regulations on medical devices management under Decree 36/2016/ND-CP[5] and Decree 169/2018/ND-CP[6] in particular applying Value Added Tax (VAT) to imported medical devices.

Issue description

According to Decree 36 and Decree 169, the classification of medical devices is implemented by classifying organisations that have declared eligibility to categorise medical devices.

However, based on Article 1.8, Circular 26/2015/TT-BTC,[7] the customs authorities still require companies to provide certification by the Ministry of Health for imported medical devices. Specifically, certification of the Ministry of Health is required to apply VAT of 5 percent for medical equipment and chemicals used for testing and sterilisation which is not listed under Circular 26/2015/TT-BTC and Circular 83/2014/TT-BTC.[8] Therefore, VAT of 5 percent cannot be applied for many imported products which are medical devices as defined by Decree 36 and Decree 169, such as:

- Class A medical devices that already have the certification of declaration of applied standards issued by a Department of Health in line with Decree 36 and Decree 169;
- Medical devices that have been classified as B, C or D by a classifying organisation which are not in the required import license list under Circular 30/2015/TT-BYT;[9]
- Raw materials, software, accessories and medical gas identified as medical devices and classified under group A, B, C, or D.

In regard to this issue, the Ministry of Health has sent several official dispatches to and had exchanges with the Ministry of Finance regarding implementation of Decree 36 and Decree 169. However, until now, the customs authorities still require companies to provide certification of the Ministry of Health for imported medical devices to be eligible for the 5 percent VAT rate.

EuroCham appreciates the Office of the Government's alignment with our position. At EuroCham's Dialogue with the Prime Minister's Advisory Council for Administrative Procedure Reforms (ACAPR) on 12 December 2019, Minister-Chairman of the Government Office agreed that requiring certification of medical devices following Circular 26 is an unnecessary procedure, an administrative barrier which needs to be removed. We therefore

3 "Foreign enterprises dominate the medical devices market", *VnExpress*, 26 July 2018. Available at <https://vnexpress.net/kinh-doanh/doanh-nghiep-ngoai-chiem-linh-thi-truong-thiet-bi-y-te-3782917.html>, last accessed on 17 February 2019.
4 'The medical devices market is over 1.1 billion USD with 90% from imports', *Saigon Times*, 27 July 2018. Available at: <https://www.thesaigontimes.vn/275877/thi-truong-thiet-bi-y-te-hon-11-ti-do-la-nhung-nhap-khau-tren-90.html>, last accessed on 17 February 2019.
5 Decree 36/2016/ND-CP dated 15 May 2016 of the Government on medical devices management.
6 Decree 169/2018/ND-CP dated 31 December 2018 of the Government amending Decree 36.
7 Circular 26/2015/TT-BTC dated 27 February 2015 of the Ministry of Finance guiding value-added tax implementation and tax management.
8 Circular 83/2014/TT-BTC dated 26 June 2014 of the Ministry of Finance guiding the application of value-added tax according to Vietnam's list of Imports.
9 Circular 30/2015/TT-BYT dated 21 October 2015 of the Ministry of Health on importing medical devices.

expect immediate actions to be taken by the customs and tax authorities to address this administrative barrier.

We understand that the Ministry of Finance is drafting a Circular amending and supplementing Circular 83/2014/TT-BTC and guiding documents. However, we note that Circular 26/2015/TT-BTC is also a major challenge that requires the attention of MOF. This is the long-term issue and has affected deeply the importing medical devices activities.

Potential gains/concerns for Vietnam

As mentioned above, 90 percent of medical equipment is imported from foreign countries to meet the medical examination and treatment needs of hospitals, of which public hospitals account for 70 percent of the market share. The inconsistency in the implementation of legal regulations related to the import of medical equipment, especially the issue of VAT rate for these items, has caused great difficulties for importers as well as public hospitals over the last years. Currently, importers are paying a VAT rate of 10 percent on imported items which are defined as medical equipment according to Decree 36 and Decree 169.

Recommendations:

Therefore, we respectfully recommend the General Department of Taxation and General Department of Customs:

- Be consistent in implementing regulations on classification and certification of medical devices, following Decree 36 and Decree 169;
- Apply a consistent rate of VAT for imported medical devices;
- Issue a guiding document on applying VAT for imported medical devices as soon as possible; and
- Amend Circular 26/2015/TT-BTC on VAT for medical devices to be in line with Decree 36 and Decree 169. We recommend MOF provide a detailed timeline for amending Circular 26/2015/TT-BTC and Circular 83/2014/TT-BTC as soon as possible and publish draft amending Circulars for the public to provide comments as per the procedure of issuing legislative documents before issuance.

II. MAINTENANCE SERVICES FOR HIGH-TECH MEDICAL EQUIPMENT

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

Issue description

High-tech medical equipment refers to advanced and up-to-date technology medical systems. These medical systems are often provided with a free-of-charge warrantee for 1 year by product manufacturers / venders for all repairs, quality calibration, control and damaged part replacement. However, for this technology, the product life cycle will last typically 10 years if it is under proper service maintenance by product owners or its qualified service providers.

The nature of high-tech and sophisticated medical equipment and its use in critical diagnostic and/or treatment with patients oblige that all features are available exactly in the way they were developed in order to fulfil the needs for which they were conceived, i.e. the performance and operation environment must be maintained in optimum condition. In order to ensure this, products must be quality controlled, calibrated and maintained on a daily/weekly/monthly and yearly basis according to the manufacturer's indications with appropriate tools, original spare parts and following the processes specially designed for this purpose.

When those activities are properly done, systems will always meet the specified technical specification, optimal performance, give the proper diagnosis/treatment quality and will ensure its long-life cycle, avoid over-depreciation, in correct use conditions.

Current practice is that almost all high-end medical equipment owners and/or users are currently not following

manufacturers' regulations/ recommendations. They apply only a very poor corrective maintenance on systems, not always with original spare parts and/or tools. This practice is not sufficient to prevent failures, nor does it assure a correct performance and productivity of the systems or fulfil the minimum quality requirements. There is an unclear understanding of the related risks when adopting this practice, which may even include problems with quality of diagnostic and treatment procedures.

Article 57.2.b under Decree 36/2016/ND-CP[10] has mentioned that medical establishments are required to perform periodical maintenance, calibration, control/test for medical instruments in use as per requirements by product owners. However, this is just a general regulation, which does not yet cover all aspects such as clear guidance on what criteria to perform, process to define qualified service providers, purchasing requirements, budget allocation etc.

Potential gains/concerns for Vietnam

Due to the gap of unclear regulation in place, almost all medical equipment at medical establishment sites, especially government public users, are not maintained properly or on time. There are many cases where the maintenance has been done by unqualified service providers, not duly authorized by product owners/manufacturers and without providing original replacement parts, and instead using parts which are not compatible with such systems. This general practice cannot ensure good quality of maintenance/calibration/control nor does it comply with manufacture quality requirements. Additionally, there are no controls on the qualifications of the resources involved in the maintenance of the systems (such as which technical knowledge and respective certification should be mandatory and controlled before touching any system).

In public institutions, there is no legal basis to propose the needed budget allocation for repairs and replacement, or they are just allowed for very minor and ad-hoc repair/replacement. No separate purchasing process is in place, there is no policy to approve these service activities and currently following a tender process requirement for these cases is too complicated, takes long time, and frequently is not approved.

Those systems and solutions are most of the time high-value medical equipment with complex technology and frequently representing a strong finance and effort for the institutions. Proper maintenance and use of original spare parts and consumables allows not only a benefit for patients since they are much safer, and it is also a clear financial advantage in that it prolongs the life of systems with an optimum level of performance. The total cost of ownership will be optimised with such practices.

In the private sector a similar situation is common, so similar recommendations apply for the benefit of patients and institutions.

Recommendations

We would like to propose that the Government:

- Requests equipment owners to review instrument status regarding performance, history of maintenance, calibration, control activities to relevant authorities if current operation is met with manufacturers' requirements/ recommendation or not. If not, present the plan for correction and preventive actions;
- Have stricter inspection and appropriate sanctions regarding requirements for medical establishments as mentioned in Chapter VIII, Decree 36/2016/ND-CP;
- Establish clear guidance regarding maintenance criteria, separate purchasing process, and budget allocation strategy for medical instrument repair and replacement;
- Create the framework for managing complex systems and solutions with rules and mandatory good practices, including proper qualification of companies/entities entitled to perform maintenance and use of original/ certified and compatible spare parts; and
- Whenever possible, promote the acquisition with extended warranty including all spare parts, consumables and qualified labour for at least 5 years (ideally for the total expected life circle).

10 Decree 36/2016/ND-CP dated 15 May 2016 of the Government on medical devices management.

III. MANAGEMENT OF MEDICAL DEVICES IN VIETNAM

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

An aging global population and an increase in chronic disease have led to the accelerating demand for healthcare. The need to treat more and more patients for less money has created a demand for outcome-based measures in global healthcare systems and Vietnam is no exception. The prevalence of non-communicable diseases in Vietnam has increased significantly in recent years. These diseases now contribute to around 79 percent of cases of mortality.[11] The most frequent diseases are cancer, heart and vascular disorders, diabetes, and Chronic Obstructive Pulmonary Disorder (COPD).

Out-of-pocket healthcare spending, meanwhile, remains a significant burden for households. The indirect costs of healthcare such as travelling, meals during hospitalisation and loss of income during treatment puts patients and their families under enormous financial pressure. In the absence of professional and organised homecare services, patients tend to care for themselves with the help of their family. This causes a lot of concern to patients and potential additional health complications due to the lack of professional follow-up. Moreover, in most cases, patients will return to hospital several times and, for some, with more severe conditions.

Consequently, there is a pressing need for more efficient healthcare solutions enabled by innovative and cost-effective digital tools and devices.

1. Professional homecare

Issue description

We note that MOH is accelerating actions to overcome the challenge of overcrowded hospitals, following the Government's scheme to address hospital congestion.[12] But even healthcare systems with greater bed capacity have established homecare services to improve the follow-up of chronic and long-lasting diseases for patients who return to their homes to continue treatment after being discharged from hospital. In the EU, 1 in 5 households in need of help due to long-term health problems use professional homecare services.[13] Homecare is promoted to allow people to stay in their homes rather than use residential, long-term, or institutional-based nursing care. It would therefore enhance patient access to treatment, especially those suffering from chronic diseases.

A viable solution for the increasing trend of chronic diseases is encouragement and development of professional homecare services and home-treatment which consequently reduces the cost of hospitalisation that long-term patients need to cover. Intervention for behavioural change for patients, care givers and healthcare professionals would be critical provided that healthcare systems can further enhance integration and coordination. Developing home care guidelines and policies for chronic diseases would be an important factor to encourage healthcare professionals to consult patients about adopting homecare as a treatment option.

With the support of innovative medical devices and equipment, Vietnamese patients would have access to new models of healthcare which can improve treatment in the home, such as renal dialysis, or enable better control of chronic wounds. Many other medical services can also be conducted in the home with the help of healthcare professionals' remote guidance.

Homecare can help to address the problem of overcrowded hospitals, reduce high public spending on chronic diseases and mitigate out-of-pocket healthcare spending for households. At the same time, it can help to improve quality of life for all patients suffering from chronic diseases.

11 "Non-communicable disease mortality accounts for 79%", *Nhan Dan Online*, 25 October 2019. Available at: <https://www.nhandan.com.vn/y-te/tieu-diem/item/42018802-79-ca-tu-vong-do-cac-benh-khong-lay-nhiem.html>, last accessed on 8 December 2019.

12 Decision 92/QD-TTg dated 9 January 2013 of the Prime Minister on Scheme to address hospital overload during 2013-2020.

13 "1 in 5 households in need in the EU use professional homecare services", *EuroStat*, 28 February 2018. Available at: <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20180228-1?inheritRedirect=true&>, last accessed on8 December 2019.

Recommendations

We recommend MOH support the development of a home care model through:

- Supporting the creation of an official, organised system of homecare by trained professionals with adapted training, material, guidelines and protocols;
- Introducing education programs for patients and their families promoting the continuity of treatment and appropriate care protocols;
- Ensuring trained professionals (nurses, pharmacists and specialists) facilitate care outside hospitals;
- Providing relevant support policies to healthcare professionals involved in home care; and
- Supporting the registration of medical devices, ensuring import licences are approved smoothly, and consider full reimbursement for home care drug and medical devices.

2. Digitalisation

Issue description

In future, healthcare can be more integrated, value-based and with a stronger focus on patient outcomes. Digital tools will play a central role in the most promising areas of healthcare innovation. Telemedicine, Artificial Intelligence (AI)-enabled medical devices, and blockchain electronic health records are just a few concrete examples of digital transformation in healthcare. Digital healthcare solutions will support analytical capabilities, utilise the full potential of big data, consequently expand precision medicine, transforming care delivery and improving patient experience. Furthermore, enhancement of medical technology, including home modifications, would also supplement and complement traditional homecare services. People with very complex conditions may increasingly be able to remain living at home rather than in hospital or institutional care.

In Vietnam, we note that the Government had accelerated application of information technology in hospital management, development of electronic health insurance and particularly non-cash payments at hospitals in urban areas.[14] However, comprehensive actions are required to harness new technologies and adapt to the global trend of digitalisation in the healthcare sector. Challenges lie at limited infrastructure of the healthcare system which requires investments in human resources and finance.

Recommendations

We would therefore recommend the Government and MOH to:

- Have a comprehensive scheme on smart hospitals development;
- Develop a legal framework on smart hospitals and digitalisation in the healthcare system;
- Develop a data centre of electronic health records which ensure accuracy and confidentiality for patients; and
- Provide training for professionals (nurses, pharmacists and specialists) to catch up with digital age.

3. Machine installation model in hospitals

Issue description

The socialisation of medical devices is a major national policy in Vietnam. However, there remain inconsistencies in policies for the machine installation model in public hospitals among management agencies including the Ministry of Health (MOH), Ministry of Finance (MOF), and Vietnam Social Security (VSS) as presented in last year's Whitebook.

14 "Toward smart hospitals", *VnEconomy*, 10 December 2019. Available at: <http://vneconomy.vn/huong-toi-benh-vien-thong-minh-20191209214654839.htm>, last accessed 23 January 2020.

Inconsistent documents issued from VSS, MOH, and MOF on the model of placing equipment in health establishments has caused challenges for companies and health establishments when choosing the appropriate model of placing equipment in line with the current demand.

Recommendation

We respectfully request the Government and competent authorities to:

- Examine the public-private model for the healthcare sector and provide diverse and feasible socialisation models;
- As soon as possible, issue official documents of consistent policy from relevant Ministries (MOH, MOF, and VSS) regarding the model of placing equipment in public health establishments, to create an open and transparent legal framework, and;
- Circulate the documents and provide training for relevant Ministries to allow better understanding of the policy as well as full compliance with the law.

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