CHAPTER 19 INTERNATIONAL QUALITY MEDICINES (IQMED) – GENERIC AND BIOSIMILAR

PART 1: GENERICS

I. ACCELERATE THE AMENDMENT OF LAW OF PHARMACEUTICALS AND RELATED LAWS AND REGULATIONS

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

Issue description

Six years have passed since Law 105 was passed by the National Assembly Session XIII.[1] With the purpose of creating an important legal corridor to strengthen and improve the efficiency of state management, ensuring favourable conditions for Vietnam's pharmaceutical industry to develop and integrate internationally, and securing an adequate supply of quality drugs to the people, this paved the way for necessary changes.

Regardless, there is still work to be done to ensure that regulations are coherent and consistent with international best practises, reflect societal changes in the wake of the pandemic, and boost international integration.

Specifically, in the newly revised Pharma Law, two topics require amendments and supplements.

1. Extension of marketing authorisations (MAs)

According to current regulations, to extend marketing authorisations applications must be evaluated and submitted to the Council for Granting Certificates of Marketing Authorisation even if at the time of extension the technical content remains unchanged. For years, well-known, tried-and-true drugs have been sold throughout Vietnam and around the world with no complaints regarding their quality. For these drugs, Pharma Law 2016 in its current form requires a comprehensive registration procedure, like the process for first-time drug registrations. This is unnecessary and unjustified. By creating an unnecessary burden on the authorities in charge, it delays the evaluation of applications, disrupting the production, supply, and availability of drugs.

Based on international best practises, a one-step lifetime extension for drugs that have a proven safety track record should replace MA extensions. This means businesses would be able to submit a registration extension application to authorities, and it will be approved by authorities by a specified deadline. If for whatever reason the authorities cannot meet the deadline, the expiring or expired MA along with the extension application will remain valid until a new MA is issued. This change would be fully in line with the spirit of the Prime Minister's Decision 1661.[2]

2. New drugs registration process

To facilitate, accelerate and broaden Vietnamese patients' access to new therapies and drug technologies, a fast-track registration process is critical for both originator drugs and generics. The reason for this is that nowadays, generic medicines are also innovative due to process changes and R&D advances, while still providing more affordable treatment options for patients.

Patient access to better health should not be hindered by lengthy registration processes and procedures that cannot be completed, such as the Certificate of Pharmaceutical Product (CPP) requirements and document verification processes.

1 Law 105/2016/QH13 dated 6 April 2016 of the National Assembly on Pharmacy.
2 Decision 1661/QD-TTg dated 4th October 2021 on Simplification of Administrative Procedures Under Management Scope of the Ministry of Health.

Shortening registration times would benefit everyone, including:

- Patients – As more drugs and therapies become available at reduced prices, treatment outcomes will be improved.
- Businesses – By allowing more products to be registered and sold, business growth will be stimulated.
- Vietnam's economy – This will increase investment, expand the pool of pharmaceutical experts, and ensure patients' safety by building a modern domestic healthcare system.
- Authorities – It would reduce workloads and limit unnecessary burdens.

Potential gains/concerns for Vietnam

Decision 1661 of the government on the simplification of administrative procedures under the Ministry of Health's management opens the door to Law on Pharmacy revisions, specifically to allow for simplified lifetime MA extensions.

Around 13,800 MAs were due to expire in 2022. Such a great number was beyond the capacity of authorities. On 23 June 2022, 6,251 MA extensions were issued in accordance with Resolution 12[3] and Decree 29.[4] On 20 July 2022, 3,579 more MAs were extended until 31 December 2022, based on the the Drug Administration of Vietnam's Official Letter 6942.[5] However, 9,830 MAs that were extended in 2022 expired again on 1 January 2023.

At the extraordinary session of the National Assembly held held from 5 to 9 January 2023 January 2023, the National Assembly voted a resolution to allow drugs with MA expiring from 1 January 2023 to continue their MA validity until 31 December 2024. At the time of sending this position letter, Resolution 80/2023/QH15 has been published, with the above contents specified in Article 3, however the Ministry of Health shall still issue and publish the list of drugs and medicinal ingredients with MA certificates permitted to continue their validity according to the provisions of Clause 1, Article 3 of this Resolution. IQMED and the whole industry welcomed this decision.

In the Pharmacy Law and related regulations and laws, a long-term, sustainable solution that involves simplified lifetime MA extensions and the implementation of a mechanism of responsibility for authorities in the event that an extension is not made in time should be incorporated. It is also necessary to revise the procedure for registering drugs for the first time in order to unlock the full potential of the healthcare sector.

Recommendations

In the interest of the patients' wellbeing and as part of our mission, we recommend the following:

- The Ministry of Health to publish the list of Extended Marketing Authorization Certificates expired / expiring from 1 January 2023 without undue delay (i.e. before 18 January 2023) to avoid lack of medicines. All MA expiring between 1 January 2023 and 31 December 2024 shall be extended until 31 December 2024.
- Revise and redraft the Pharma Law with consideration for the comments and suggestions of the industry.
- Prepare clear guidelines regarding the introduction of a simplified MA extension process, along with clear transitional steps and implementation milestones.
- Amend first-time drug registration processes with a feasible timeline, transitional steps and milestones.
- Introduce the responsibility of authorities in the case of delays.
- Submit the new draft Pharma Law for National Assembly approval in October 2024.
- Implement regulatory coherence and adjust related regulations by January 2025.

3 Resolution 12/2021/NQ-UBTVQH15 dated 30th December 2021 of the Standing Committee of the National Assembly on Permission to Implement Certain Mechanisms and Policies in the Health Sector in Service of Covid-19 Prevention and Control Practices.

4 Decree 29/2022/ND-CP dated 29th April 2022 of the Government on detailing, and providing measures to implement, the National Assembly Standing Committee's Resolution12/2021/UBTVQH15 dated December 30, 2021, on allowing the application of a number of health-related mechanisms and policies for the prevention and control of COVID-19 pandemic.

5 Official letter 6942/QLD-ĐK dated 20th July 2022 of the Drug Administration of Vietnam on Publication of the list of drugs as prescribed in Clause 1, Article 14 of Decree 29/2022/ND-CP of CP (Phase 2).

II. EXPAND THE SCOPE OF FIE'S OPERATIONS

Relevant authorities: Ministry of Health (MOH), Office of Government (OOG), National Assembly (NA), Ministry of Planning and Investment (MPI), Ministry of Industry and Trade (MOIT)

Issue description

Foreign-invested enterprises (FIEs) in the pharmaceutical industry can currently only import and sell drugs through registered wholesalers, often local pharmaceutical companies, which then distribute them to hospitals and pharmacies. Patients' access to medicines is impacted by these limitations on FIE operations. It also demonstrates the government's hesitancy toward foreign investment.

As part of Decision 376,[6] strategies are outlined for developing the domestic pharmaceutical industry to level IV on the World Health Organisation's (WHO) classification scale, with a market value ranking amongst the top three ASEAN markets and enabling the provision of affordable, high-quality, safe, and effective medicines. In the same decision, the government focuses on attracting foreign investment for the production of patented drugs, specialised drugs, generic drugs in high-tech dosage forms, vaccines, and biological products.

But with the current regulations, FIEs investing in drug tolling and technology transfers cannot purchase products from local manufacturers and sell them to wholesalers. Therefore, FIEs' extensive expertise in drug development, sales, and marketing cannot be used to expand their business in Vietnam, domesticate high-quality drugs manufacturing, and expand treatments for patients.

In general, it is troubling that foreign investors must go through costly registration procedures but are then not allowed to undertake many activities within the sector.

Potential gains/concerns for Vietnam

Due to this limitation, foreign investment in production, tolling, and pharmaceutical technology transfer is less attractive than in other ASEAN countries. It is therefore questionable whether the government will achieve what it called for in Decision 376.

Recommendations

We would like to make the following recommendation:

- Expand the rights of FIE operations in the pharma industry, allowing them to take part in locally produced products, especially tolling and tech transfers, demonstrating that foreign pharmaceutical companies are treated unfairly in Vietnam.

III. TENDER PROCESS AT THE HEALTHCARE FACILITIES

Relevant authorities: Ministry of Health (MOH)

Issue description

Using high-quality generic drugs at health facilities has helped Vietnam's social security fund save money in recent years. However, according to the current bidding method regulated by Circular 15,[7] hospitals are counting only the quantity of drugs consumed and the annual list of drugs to plan their procurement for the next year. Within the tender invitation list, the cheapest item wins the tender. The winning tender price then becomes the planning price for the following year. Because the next year's winning price cannot be higher than the planning

6 Decision 376/QD-CP dated 17th March 2021 of the Prime Minister approving the Program on development the pharmaceutical industry and domestically produced medicinal materials to 2030, with a vision to 2045.

7 Circular 15/2019/TT-BYT dated 11th July 2019 of the Ministry of Health on providing guidance on bidding for supply of drugs for public health facilities.

price, more expensive but high-quality drugs cannot participate in this discount race, preventing them from winning the tender. This is not only harmful to the development of the pharmaceutical industry, but also to the wellbeing of patients. Companies cannot develop and supply high-quality medicines at a low cost to meet constantly decreasing prices. In fact, winning products, although in the same tender group, often do not provide the same treatment efficacy for patients. By prioritising cheap prices, doctors' choice of high-quality drugs and best treatment options are significantly limited, and out-of-pocket costs for patients grow.

Recommendations

We would like to make the following recommendations:

- Add additional criteria based on a drug's technology and efficacy to measure cost-effectiveness versus treatment quality for drugs within the same tender group.
- Diagnosis-related groups are popular throughout the world, with drug prices still being regulated by the Ministry of Health. In order to ensure the best treatment effects for patients, hospitals take proactive procurement measures based on the budget allocated. This helps to optimise all resources involved in the tender process, including human and financial resources. It doesn't put any pressure on doctors and other medical staff, as instead of being forced to choose the cheapest drug, they can choose the best treatment option. As an alternative, we recommend reviewing drugs participating in tenders according to different criteria besides price only.

PART 2: BIOSIMILARS

INCREASING PATIENT ACCESS TO STATE-OF-THE-ART THERAPIES

Relevant authorities: Ministry of Health (MOH), Vietnam Social Security (VSS), National Assembly (NA) – Committee on Social Affairs

Issue description

The development of biosimilars is an attempt to improve access challenges faced by patients, generate cost savings for healthcare systems, and increase treatment options for healthcare professionals.

Potential gains/concerns for Vietnam

Benefit for patients

The introduction of affordable, high-quality biosimilars improves access to life-changing medicines for patients worldwide. The EU saw a 100 per cent increase in the use of biologic treatments after the introduction of biosimilars.[8] The overall trend in Europe is that biosimilar medicines are increasingly being used in medical practise and are increasing access to medicines for both chronic and acute care in areas such as cancer, diabetes, rheumatoid arthritis and other diseases linked to the immune system.

Women, the elderly, and lower-income individuals would disproportionately benefit from access to biosimilar medicines. At least 400 million people worldwide cannot access essential health services and more than two billion cannot afford to buy the medicines they need.

8 "Biosimilars", US FDA. Available at: <www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/> last accessed on 28 January 2019; "Delivering on the Potential of Biosimilar Medicines", IMS Institute for Healthcare Informatics (2016). Lin-Chau Chang, Journal of Food and Drug Analysis, 27 (2019) 671-678; Isaacs J, et al. Considerations Med 2017, 1:3–6; Anita Krishnan et al. Biosimilars 2015:5 19–32. Kumar, J. et al., Pharmacovigilance 2015, S3; Richard Markus et al. BioDrugs (2017) 31:175–187; Jun Wang et al. Pharmaceuticals 2012, 5, 353-368; The Biosimilars Council 2017: Biosimilars in the US – Providing more patients greater access to lifesaving medicines. Available at: <http://pr.euractiv.com/pr/biosimilar-medicines-opportunity-dramatic-increase-patient-access-across-europe-153876>, <www.medicinesforeurope.com/biosimilar-medicines/our-5-pillars/>, </www.karger.com/Book/Toc/279159>, last accessed on 18 February 2021.

Benefit for healthcare practitioners

The introduction of biosimilars drives competition, resulting in increased treatment options and value-added services to support patient care and the healthcare community. Since 2006, EU-approved biosimilar medicines have generated more than 400 million patient days of clinical experience worldwide. With the global prevalence of age-related chronic diseases rising, access to cost-effective medical treatment will become increasingly important over the next decades.

Benefit for payers

Moreover, competition increases the affordability of biologics, which results in savings for healthcare systems, helping to liberate resources that can be used to improve care and fund next-generation medicines. Globally, biosimilar medicines have the potential to offer healthcare systems huge savings for the same outcomes.

Health economic benefits from Biosimilar Medicines

Given ageing populations and the rising prevalence of chronic conditions and cancers for which biologics are used, biologics take up a large part of healthcare budgets, which are already under immense pressure, and rationing measures are inevitably applied.

However, just as the introduction of generic versions following patent expiry of small molecule drugs drove down prices, biosimilars can be expected to lower the prices of biologics. The substantial savings realised can improve patient access by allowing more patients to be treated from the same budget. Thus, biosimilars will enable stakeholders – including payers, clinicians, and patients – to benefit from a greater choice of treatment options, and more patients will have access to these treatments. By introducing competition with biosimilars, the savings generated could reach between $44 billion and $250 billion over a ten-year period in the U.S., with the value dependent upon the policy adopted in the coming years. Other research has shown that opening markets to biosimilar competition could have enabled healthcare systems to realise savings of more than 10 billion euros in the EU's five major markets (the UK, Germany, France, Spain, and Italy) between 2016 and 2020, based solely on direct competition for the originator molecule. The cumulative savings opportunity for biosimilars from 2021 to 2026 is estimated at $285 billion globally. Further savings are possible through indirect competition for other in-class or therapy-area-specific product sales. Access to cost-effective treatment is paramount for the short-, medium-, and long-term sustainability of healthcare systems. Biosimilar medicines represent a cost-effective alternative to the reference products.

Recommendations

We would like to make the following recommendations:

- Consider the early issuance of guidance for biosimilar dossier technical appraisals.
- Include a specific definition for biologics that are not approved as a biosimilar, such as bioscopies and noncomparable biologics, in the Pharma Law to help healthcare professionals have accurate and complete understandings about circulating biologics.
- Consider the early issuance of healthcare professional guidance for using biosimilars in clinical practise to improve patient treatment efficacy and safety.
- Increase biosimilar's medical educational and training activities to healthcare professionals and healthcare authorities for improving knowledge.

ACKNOWLEDGEMENTS

The International Quality Medicines - Generic and Biosimilar Sector Committee

CHAPTER 20 **MEDICAL DEVICES AND DIAGNOSTICS**

OVERVIEW

The World Health Organisation (WHO) has repeatedly emphasised the importance of medical equipment for a wide range of interventions, from sprains to more complex procedures such as HIV/AIDS diagnosis and organ transplants. Medical equipment is widely and comprehensively applied for the healthcare of patients across many disciplines, including specialised and grassroots medicine, primary care, preventive medicine, diagnostics, acute and chronic treatment, palliative care, functional rehabilitation, and research. Thus, along with medicine and physicians, medical equipment is considered one of the three main pillars of health work.

In that spirit, EuroCham's Medical Devices and Diagnostics Sector Committee is committed to always cooperating fully and closely with the government of Vietnam to promote the common goals of increasing access to affordable high-quality medical equipment and ensuring the sustainable development of the environment while complying fully with Vietnam's medical equipment management guidelines, policies, and laws.

The role of medical equipment became increasingly evident during COVID-19 prevention and control. Recognising the importance of medical equipment, for the past five years, the government of Vietnam has continuously updated and perfected medical equipment management regulations in the direction of publicity, transparency, and international integration. Specifically, on 8 November 2021, the government issued Decree 98[1] on the management of medical devices to replace Decree 36[2], Decree 169[3], and Decree 03[4].

Decree 98 is a major reform in the management of the medical equipment industry, with a focus on thorough administrative procedure reforms, and it changed marketing authorisations from pre- to post-audit.

We recognised the following improvements:

1. It published the standards for class B medical equipment and the mechanism for recognising other countries' marketing authorisation results for class C and D medical equipment, reduced licencing times, and made the entire marketing authorisation process public and transparent;

2. It eliminated the procedure for announcing eligibility for medical equipment classification, adjusted the certification of medical equipment advertisements, and simplified publication procedures for production, sale, and consultation by allowing online declarations, eliminating the need for a receipt from the management agency; and

3. Since marketing authorisation numbers are now valid indefinitely, enterprises are no longer required to renew them, but are responsible for updating any changes, if any, during widespread use of the equipment.

Along with Decree 98, the institutional system for managing medical equipment is also reflected in numerous legal documents such as the Law on Medical examination and treatment[5], Law on Product quality[6], Law on

1 Decree 98/2021/ND-CP dated 08 November 2021 of the Government on Medical equipment management.
2 Decree 36/2016/ND-CP dated 15 May 2016 of the Government on Medical equipment management.
3 Decree 169/2018/ND-CP dated 31 December 2018 of the Government amending and supplementing a number of articles of Decree 36/2016/ND-CP dated 15 May 2016 of the Government on Medical equipment management.
4 Decree 03/2020/ND-CP dated 1 January 2020 of the Government amending and supplementing Article 68 of Decree 36/2016/ND-CP dated 15 May 2016 of the Government on Medical equipment management was amended and supplemented in Decree 169/2018/ND-CP dated 31 December 2018 of the Government amending and supplementing a number of articles of Decree 36/2016/ND-CP dated 15 May 2016 of the Government on Medical equipment management.
5 Law on Medical examination and treatment 40/2009/QH12 of the National Assembly of Vietnam dated 23 November 2009.
6 Law on Product quality 05/2007/QH12 of the National Assembly of Vietnam dated 21 November 2007.

Commerce[7], Law on Standards and Technical regulations[8], Law on Advertising[9], Law on Bidding[10], Law on Price[11], and so on.

The health sector still faces practical problems that have not been codified or included in legal documents. To ensure specificity, feasibility, synchronisation, and international integration, many contents of state management of medical equipment need further study and review.

I. THE MODEL OF PLACING AND BORROWING INSTRUMENTS AT PUBLIC HEALTH FACILITIES

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

Currently, most hospitals across the country use the winners of the bids for machines placed and borrowed to provide materials and chemicals for diagnosis and treatment. According to statistics from major hospitals, 90 per cent of testing machines are borrowed or placed[12]. The placement instrument model is the model where a company winning a bid supplies materials and/or chemicals to a procuring entity.

Essential technical services include medical tests in haematology, biochemistry, immunology, immunohistochemistry, molecular biology, blood screening and so on. Medical testing techniques require the installation of equipment, machines, software, and accessories. The installation of the complete system to operate medical tests is carried out by the winners of the bid for supplying chemicals and materials, including medical equipment distributors or suppliers.

The payment for laboratory technical services is covered by insurance according to the specified price range for each technical service performed.

This model of paying for actual tests and placing machines has been applied for more than a decade in Vietnam. Many governments, including G7 member countries, recommend it due to its benefits, such as maintaining a balance between the state budget and the hospital's finances while ensuring healthcare for the people[13].

However, although this model has been implemented for many years, public health facilities and businesses are currently facing difficulties due to the lack of a specific and unified guiding document jointly issued by the Ministry of Health (MOH), the Ministry of Finance (MOF), and Vietnam Social Security (VSS) as presented in EuroCham's 2019[14], 2020[15], and 2021[16] Whitebooks, as well as in other EuroCham documents in 2022.

7 Law on Commerce 36/2005/QH11 of the National Assembly of Vietnam dated 14 June 2005.
8 Law on Standards and technical regulations 68/2006/QH11 of the National Assembly of Vietnam dated 29 June 2006.
9 Law on Advertising 16/2012/QH13 of the National Assembly of Vietnam dated 21 June 2012.
10 Law on Bidding 43/2013/QH13 of the National Assembly of Vietnam dated 26 November 2013.
11 Law on Prices 11/2012/QH13 of the National Assembly of Vietnam dated 20 June 2012.
12 "Bộ Y tế đề nghị tiếp tục thanh toán BHYT với dịch vụ xét nghiệm từ máy mượn, đặt tại các cơ sở y tế" [Ministry of Health proposes to continue paying for insured testing services on borrowed or placed machine at health facilities], Government e-Newspaper, 23 May 2022. Available at: <https://baochinhphu.vn/bo-y-te-de-nghi-tiep-tuc-thanh-toan-bhyt-voi-dich-vu-xet-nghiem-tu-may-muon-dat-tai-cac-co-so-y-te-10222052317335398.htm>, last accessed on 02 August 2022.
13 Global map of medical devices, WHO Medical Devices Technical Series, 2017, page 81. Available at: <https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/>, last accessed on 2 August 2022.
14 Whitebook 2019, EuroCham.
15 Whitebook 2020, EuroCham.
16 Whitebook 2021, EuroCham.

Potential gains/concerns for Vietnam

The model of placing instrument at public medical facilities has been used over a decade but still has not been recognised in any official legal documents.

From 2018 to mid-2022, the MOH, MOF, and VSS promulgated many guiding documents on the use of placed or borrowed machines and payments for insured services performed on placed or borrowed machines. The issuance of many different documents has made it difficult for hospitals and businesses to choose the right machine installation model as well as the way to handle already installed machines. Businesses are under considerable pressure as they receive requests for donating or leasing machines at symbolic prices.

Since the model of placing and borrowing instrument has not been legalised yet, it creates controversies for agreeing on insurance payment for tests being done on placed instruments. We are afraid that this could cause delays in testing, diagnosing and treating patients.

After receiving feedbacks from hospitals and enterprises, Resolution 144/NQ-CP on the guarantee of drugs, medical equipment and payment of medical examination and treatment expenses under health insurance issued on 05 November 2022 by the Government, allowing the place instrument model at public medical facilities and insurance payment for tests done on the placed/borrowed machines until 05 November 2023. However, this is only a short-term solution and has not completely solved the difficulties of enterprises.

Machine donation request

Member companies of the EuroCham are not able to donate machines for the following reasons:

First, receiving a donated machine is likely to be a violation of anti-corruption laws. Article 22 of the Law on Anti-corruption[17] specifies, "Agencies, organisations, entities and office holders must not directly or indirectly receive gifts in any form from agencies, organisations, units and individuals related to the work they are performing or under their management." Thus, public hospitals should refuse gifts from the winning bidder for chemical supplies.

Second, the receipt of the donated machine could be seen as lacking publicity and transparency in the chemical procurement process. If a hospital received a donated machine that runs a closed technology by an enterprise, the machine can only be operated using chemicals provided by that enterprise. Therefore, proving transparency and publicity in the process of winning the bid for supplying chemicals is difficult and may unintentionally create a loophole for future problems.

Third, according to the business code of conduct and internal rules of member companies, machine donation is considered inappropriate.

Fourth, equipment and machinery are of great value, therefore, machine donation would place a large financial burden on businesses.

Machine renting

According to the Law on Management and Use of Public Property[18], Decree 151[19] along with feedback from businesses and medical facilities, the machine renting procedure is very complicated because it involves the preparation of an analysis plan, approval by relevant authorities, and the organisation of centralised bidding for machine rentals.

Especially cumbersome is that there are no specific and clear instructions on how to determine rental prices. Several hospitals suggested a symbolic rental price, whereas businesses prefer that it be equal to the rental price on the market for the same type of product, in order to cover depreciation, maintenance, and other reasonable expenses related to the products.

17 Law on Anti-corruption 36/2018/QH14 of the National Assembly of Vietnam dated 20 November 2018.
18 Law on Management and use of public property 15/2017/QH14 of the National Assembly of Vietnam dated 21 June 2017.
19 Decree 151/2017/ND-CP dated 26 December 2017 of the Government detailing a number of articles of the Law on Management and use of public property.

Our concern is that diagnostic tests and treatment will be disrupted, particularly critical rapid tests that are crucial to a patient's life such as blood screenings and surgery, and that if the machine is no longer used, advanced and modern testing techniques will not be available and patients will lose opportunities to access to advanced and mordent testing techniques.

Recommendations

We would like to make the following recommendations:

- Incorporate the model of machine borrowing and placement into the law, specifically in the amended Law on Medical Treatment and Examination and the amended Law on Tender and organise the training for relevant key stakeholder for implementation.

II. MARKETING AUTHORISATION FOR CLASS C AND D MEDICAL DEVICES

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

Issue description

The number of applications for marketing authorisation for Class C and D medical devices that have already been submitted from 1 January 2022 and are going to be submitted under Decree 98 is estimated to be around four to five thousand applications. However, there has only been around 12% of marketing authorisation granted as of January 2023.

Potential gains/concerns for Vietnam

As a result, on 01 January 2023, all the import licenses for class C and D medical devices (issued under Circular 30/2015/TT/BYT, Circular 47/2010/TT-BYT) and all marketing authorisation numbers for class C and D medical devices (issued under Circular No. 44/2014/TT-BYT) have already expired. This worsens the existing nationwide shortage issue of medical devices and consequently affects the quality of examination and treatment for patients.

The MOH has already submitted a Draft Decree amending and supplementing a number of articles of the Decree 98/2021/ND-CP which contains the extension of the validity of the current import licenses and marketing authorisation numbers for class C and D medical devices. However, it still has not been promulgated.

Furthermore, since there are already thousands of applications awaiting to be appraised, new products trying to obtain marketing authorisation numbers would be put at the back of the queue. This prevents new technology and advanced machinery from entering the market.

Recommendations

We would like to make the following recommendations:

- Appraise and grant marketing authorisation for class C and D medical devices as soon as possible.
- The Draft Decree amending and supplementing a number of articles of the Decree 98/2021/ND-CP shall be issued as soon as possible to ensure the continuance of importing and circulating class C and D medical devices in the meantime.
- Consider a fast track for new products so that they can enter the market faster and medical professionals and patients can have access to new and more advanced technology.

III. REMANUFACTURED MEDICAL DEVICES

Relevant authorities: Office of Government (OOG), Ministry of Health (MOH), Ministry of Industry and Trade (MOIT)

Issue description

To ensure all people have access to a high-quality, safe, and effective healthcare, the regulatory environment in the health sector should be capable of effectively controlling the quality and safety of medical and diagnostic equipment imported or domestically manufactured, while facilitating the adoption of new products and business models quickly and transparently to bring clinical and economic benefits to the country.

These principles also apply to remanufactured medical devices by preventing the free import of used medical devices for medical use but still facilitating the import of remanufactured medical devices. Considering that this category is beneficial in certain circumstances, it should be clearly regulated.

Potential gains/concerns for Vietnam

Remanufactured medical devices are widely used around the world, including in the U.S., Europe, Australia, Japan, and so on. In this device category, high-quality medical devices or accessories are purchased at a lower cost than they would otherwise be, contributing to environmental sustainability while reducing the amount of input materials required to manufacture new products, which impact the environment adversely. Nearly 20 per cent of diagnostic imaging systems sold in countries such as the U.S. and Germany are remanufactured.[20]

In fact, modern high-value large devices often have a very long shelf life, even up to 30 years with good maintenance. However, due to demand, many medical facilities replace these devices after just five to ten years of use with more advanced ones. Discarding such devices is a huge waste. As a result, original equipment manufacturers (OEMs) often repurchase for refurbishment after a rigorous procedure resulting in affordable new products with the same technical standards as a brand-new device, allowing medical facilities, especially smaller ones, to meet their needs.

In addition, OEMs accept spare parts for these devices for repair and refurbishment instead of producing new ones.

The strict and careful process of recalling, receiving, and refurbishing is carried out by OEMs in compliance with the standards prescribed by state management agencies, from receipt to market placement and after-sale services.

Vietnam recently entered into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) effective from 14 January 2019 and the European-Vietnam Free Trade Agreement (EVFTA) effective from 1 August 2020. In Article 2.6 of the EVFTA, both parties committed to treating remanufactured goods the same as new goods[21]. Accordingly, remanufactured goods can be imported at preferential tariffs if they have a Certificate of Origin under the EVFTA. After being remanufactured, modern medical devices meeting the criteria in Article 2.3k[22] can be exported to Vietnam or the EU as normal goods.

This is important because besides fulfilling demand, developing remanufactured goods is a new trend of the future given the increasingly scarce sources of raw materials, especially precious and valuable raw materials. With the development of science and technology and the increasing demand for environmental protection and resource-saving, the use of remanufactured goods will become more and more popular[23]. Compliance with the

20 "Refurbishment of Medical Equipment Report on promising KETs-based product nr. 4", *European Commission,* Available at:< https://ati.ec.europa.eu/sites/default/files/2020-05/analytical_report_nr4_refurbishment_final.pdf>, last accessed on 9 August 2022.

21 Article 2.6 EVFTA.

22 Article 2.3k EVFTA: "remanufactured good" means a good classified in HS Chapter 84, 85, 87, 90 or heading 94.02, except those listed in Appendix 2-A-5 (Goods Excluded from the Definition of Remanufactured Goods), which: (i) is entirely or partially comprised of parts obtained from goods that have been used beforehand; and (ii) has similar performance and working conditions as well as life expectancy compared to the original new good and is given the same warranty as the original new good.

23 "Đề xuất điều kiện nhập khẩu hàng hóa tân trang" [Proposed conditions for importing remanufactured goods], *Government e-Newspaper* dated 10 September 2021, Available at:< ttps://baochinhphu.vn/de-xuat-dieu-kien-nhap-khau-hang-hoa-tan-trang-102300166.htm>, last accessed on 11 August 2022.

commitment in the EVFTA and CPTPP will create favourable conditions for the trade and business exchange of this special product category between Vietnam and the EU.

We welcome the MOIT's consultation on the Draft Decree on Import Management of Remanufactured Goods, as stipulated in the CPTPP. However, so far the draft has not been approved by the government. This delay has created many difficulties for enterprises producing remanufactured devices or importing them from CPTPP countries.

Recommendations

The government of Vietnam should issue and approve a management policy that allows the import and trading of remanufactured medical devices in accordance with the agreements signed between Vietnam and its trading partners.

ACKNOWLEDGEMENT

The EuroCham Medical Devices and Diagnostics Sector Committee