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Economic Cooperation



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TRADE IN REMANUFACTURED GOODS IN APEC: THE CASE OF REFURBISHED MEDICAL IMAGING DEVICES

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ACRONYMS

AMDD	Association of Southeast Asian Nations Medical Device Directives
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
BOI	Thai Board of Investment
CAB	Conformity Assessment Body
CAGR	Compound Annual Growth Rate
CBP	Customs and Border Protection (U.S.)
CE	Conformité Européenne
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
COVID-19	Coronavirus disease 2019 caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
CSDT	Common Submission Dossier Template
CT	Computed Tomography
DITTA	The Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
DMEC	Department of Medical Equipment and Construction (Viet Nam)
ECMO	Extracorporeal Membrane Oxygenation
EU	European Union
FDA	Food and Drug Administration (U.S.)
FTA	Free Trade Agreement
FTC	Federal Trade Commission (U.S.)
GDP	Gross Domestic Product
GRP	Good Refurbishment Practice
GRPMD	Good Refurbishment Practice for Medical Devices

GRP WG	Good Refurbishment Practice Working Group
IAMERS	International Association of Medical Equipment Remarketers and Servicers
IEC	International Electrotechnical Commission
IEC PAS	International Electrotechnical Commission Publicly Available Specification
ISO	International Organization for Standardization
IV	Intravenous
JIRA	Japan Medical Imaging and Radiological Systems Industries Association
LSIF	Life Science Innovation Forum
MAG	Market Access Group
MDA	Malaysia Medical Device Authority
MITA	Medical Imaging and Technology Alliance
MOH	Ministry of Health
MRI	Magnetic Resonance Imaging
NEMA	National Electrical Manufacturers Association
OEC	Observatory of Economic Complexity
OEM	Original Equipment Manufacturer
PAS	Publicly Available Specification
PPE	Personal Protective Equipment
QMS	Quality Management Systems
RHSC	Regulatory Harmonization Steering Committee
SUD	Single Use Device
USD	United States Dollar
USITC	U.S. International Trade Commission
USMCA	United States-Mexico-Canada Agreement
USTR	Office of the United States Trade Representative

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EXECUTIVE SUMMARY

The COVID-19 global pandemic has underlined the need for wider access and availability for high quality and affordable medical devices, including medical imaging equipment, as healthcare systems worldwide experienced declines in revenue while healthcare spending increased. Refurbished medical devices can offer Asia-Pacific Economic Cooperation (APEC) economies worthwhile options for their healthcare spending during and after the pandemic. When refurbished and serviced by qualified companies, refurbished medical devices offer high quality medical technology safely, effectively, and affordably. However, the importation and distribution of refurbished medical devices in some APEC economies are restricted due to refurbished devices being conflated with “used” equipment.

The benefits and treatment of refurbished medical devices are consistent with those of a broader category of remanufactured goods, as promoted by the APEC Market Access Group (MAG) Pathfinder initiative launched in 2011. The APEC Pathfinder initiative conducted several workshops between 2011 and 2018 to educate APEC economies about remanufactured goods, including differentiating remanufactured goods from used goods in domestic regulations. Since that time, numerous APEC economies (including participants and non-participants to the Pathfinder) have entered into trade agreements featuring provisions on remanufactured goods. These agreements include the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the United States-Mexico-Canada Agreement (USMCA).

Given the relevance and potential benefits of refurbished medical devices to APEC economies at this unique moment in time, this report aims to reemphasize the importance of remanufactured goods to the APEC region through the lens of refurbished medical devices. For ease of analysis, the report specifically drills down on medical imaging devices. It begins with definitions of refurbished, remanufactured, and used medical devices, and briefly describes the refurbished medical device value chain to illustrate the important roles that original equipment manufacturers (OEMs), service providers, resellers, and industry associations play in the trade of these devices. For example, the authors consulted with the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA) when drafting this report.

The report also presents brief case studies on four APEC economies (Malaysia, Thailand, United States, and Viet Nam) to illustrate the current state-of-play for market access of refurbished medical devices across the APEC region. COVID-19 has had severe economic impacts on APEC economies with clear effects on current and projected healthcare spending and service delivery. The economies chosen for the case studies illustrate varying degrees of openness to the importation/trade of refurbished medical devices. In some cases, economies’ restrictions on the importation of these devices are inconsistent with commitments made under regional free trade agreements such as the CPTPP. Other APEC economies appear willing to consider refurbished devices and are drafting domestic regulations.

The report concludes with recommendations for future opportunities, including working through APEC fora such as the MAG, to further promote the use of refurbished medical devices and remanufactured goods overall. These recommendations focus on continuing the work started by the APEC Pathfinder initiative to include technical assistance to APEC economies as well as targeted APEC-wide workshops and trainings regarding refurbished medical devices, and supporting the widespread use of International Standard IEC 63077:2019 “Good Refurbishment Practices for Medical Imaging Equipment” to harmonize terminology and requirements for refurbishment practices globally

INTRODUCTION

I.1 BACKGROUND

Remanufactured goods offer multiple benefits for APEC economies, including decreasing spending, reducing waste, contributing to greener and more circular economies, and conserving resources. Recognizing this, APEC has conducted extensive work in promoting remanufactured goods under the APEC MAG. In 2011, APEC endorsed the APEC Pathfinder on Facilitating Trade in Remanufactured Goods, an initiative where 11 economies agreed to share information on best practices and encourage capacity-building efforts to help economies identify remanufactured goods at the border and distinguish them from used goods. The participating 11 members are: Australia, Canada, Chile, Japan, Mexico, New Zealand, United States, Papua New Guinea, Korea, Singapore, and Chinese Taipei.

The 11 economies agreed to:

- Apply import-related measures specifically concerning used goods only to used goods and refrain from applying them to remanufactured goods.
- Refrain from applying import prohibitions against remanufactured goods or against remanufactured goods in specific sectors.
- Treat remanufactured goods like corresponding new goods when applying tariffs or other border charges.
- Generally apply pertinent technical regulations, conformity assessment procedures, and documentation and import licensing requirements concerning new goods to remanufactured goods.¹

Between 2011 and 2018, the Pathfinder initiative launched numerous trainings and workshops to promote trade of remanufactured goods in the APEC region. In 2020, given the urgency of addressing the COVID-19 pandemic, the APEC MAG sought to revive the discussion on remanufactured goods, with a particular emphasis on refurbished medical devices.

Although the medical technologies industry and regulators recognize distinctions between “remanufactured” and “refurbished” medical devices (see below), the medical device sector actively participates in remanufactured goods associations and has been represented within APEC-sponsored activities on this topic. Examples of active participants are medical device trade associations such as National Electrical Manufacturers Association (NEMA), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), DITTA, and the International Association of Medical Equipment Remarketers and Servicers (IAMERS) along with imaging equipment companies. IAMERS is a global organization that represents companies ranging from the largest original equipment manufacturers (OEMs) to small, highly specialized companies that sell, service, and finance previously owned medical imaging devices.

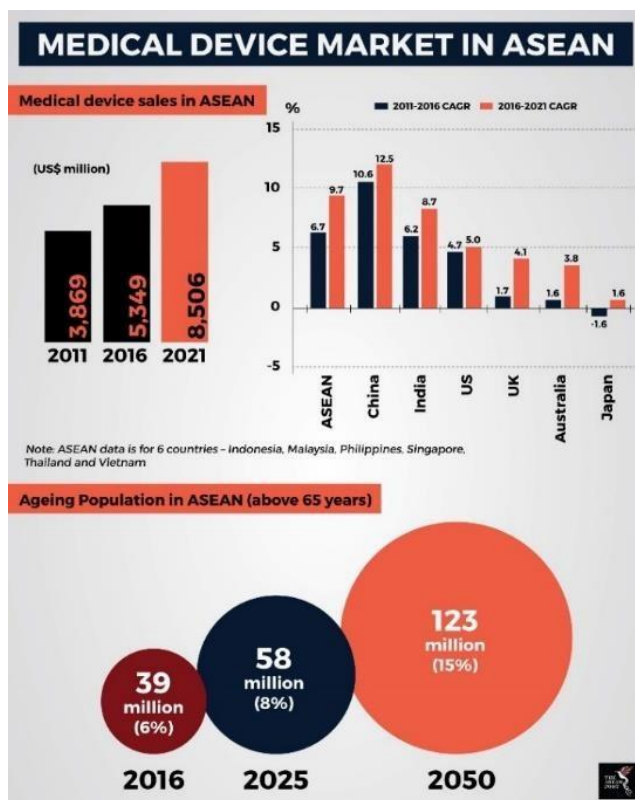
Refurbished medical devices provide a strong choice to APEC economies, and when these devices are refurbished and serviced by qualified companies, they can provide high quality medical imaging technology safely, effectively, and at an affordable cost. Public and private healthcare buyers (e.g., hospitals and private clinics) in the APEC region should have this choice available to them. However, the importation and distribution of refurbished medical devices in some APEC economies is restricted due to concerns about public health and misperceptions about refurbished devices being “used.” When

refurbished medical equipment is ensured to have the same quality, performance, safety, and intended use (including the warranty and service) as new equipment, there are no compromises on quality or safety.²

In 2017, refurbishment of medical imaging devices accounted for a global revenue of approximately \$974 million (U.S. dollars).³ The growth in the refurbished market (as exemplified for the ASEAN region in Figure 1 below) may be attributable to financial constraints caused by the high cost of new equipment and the desire to manage spending without sacrificing quality or negatively affecting public health. The COVID-19 pandemic has only increased fiscal pressures on healthcare.

For example, the need for quality healthcare continues to rise within the Association of Southeast Asian Nations (ASEAN) due to the significant increase in the aging population, among other factors, and ASEAN demand may be an indicator for what the needs are in the APEC region more broadly. It is estimated that by 2050, the number of people over 65 years of age in ASEAN will triple to 123 million (Figure 1).⁴ Refurbished medical devices can improve the likelihood that the region’s growing and aging population can access high levels of healthcare at an affordable cost.

Figure 1 Medical Device Market in ASEAN⁵



Despite their benefits, the importation of refurbished medical devices is heavily regulated and/or banned in several APEC economies. Empowering economies with the choice of purchasing affordable, high quality refurbished devices could make a difference in the domestic supply of life-saving healthcare equipment. Additionally, this need for medical equipment in the ASEAN medical device market creates strong demand, which can partly be met by allowing the sale of refurbished medical equipment. This

need, exemplified by ASEAN, can be assumed to be a similar dynamic across the APEC economies as a whole.

I.2 OBJECTIVES

By examining current practices within several APEC economies, this paper aims to stimulate dialogue within the APEC MAG on the benefits of remanufactured goods, with the focus on refurbished medical devices. The medical device sector is comprised of a wide range of products from diagnostic devices to therapeutic devices to hearing aids. To narrow the analysis and illustrate specific market dynamics, we have chosen to focus on refurbished medical imaging devices. This specific product area has also been well represented through global industry associations such as DITTA, COCIR, Medical Imaging and Technology Alliance (MITA), Japan Medical Imaging and Radiological Systems Industries Association (JIRA), IAMERS, and others, many of which contributed valuable insights to this analysis.

Our analysis included the following:

- Examining the current definitions of “remanufactured,” “refurbished,” and “used.” This is crucial as misperceptions around these definitions have resulted in market access barriers in several APEC economies.
- Reviewing the refurbished medical device value chain. This is particularly important as some market access barriers stem from concerns regarding activities of third-party refurbishers and service providers, as well as the care and maintenance of refurbished imaging devices.⁶
- Evaluating the financial considerations, along with potential benefits and challenges of trade in refurbished medical imaging devices.
- How refurbished medical devices (i.e., imaging equipment) are addressed in key free-trade agreements (FTAs), to elucidate the differences in trade agreements versus what economies in general allow regarding refurbished medical devices.
- Four APEC economy-level snapshots (Malaysia, Thailand, United States, and Viet Nam) of the treatment of refurbished medical devices.
- Recommendations for the role APEC can play on this topic in the future.

The key questions we seek to explore are:

- What regulations, service requirements, or other non-tariff measures apply to refurbished medical imaging devices?
- Can third parties import a refurbished medical imaging device by referencing the import license that the local government had issued to the OEM for the device when it was new?
- Are there procurement regulations precluding the purchase of refurbished medical imaging devices?

Please note that this report does not address the re-use of Single Use Devices (SUDs).

SCOPE DEFINITIONS AND PARAMETERS

2.1 REFURBISHED MEDICAL DEVICE TYPES: FOCUS ON DIAGNOSTIC IMAGING EQUIPMENT

Refurbished medical devices can be used in various settings, including hospitals, labs, and clinics.

Prevalent refurbished medical device categories include medical imaging equipment, such as Magnetic Resonance Imaging Equipment, X-Ray Equipment for Computed Tomography and Radioscopically Guided Interventional Procedures (with all types defined per IEC 63077),⁷ operating room and surgical equipment, defibrillators, cardiovascular and cardiology equipment, intravenous (IV) therapy systems, neurology equipment, and endoscopy equipment.

IEC 63077:2019 is the first edition of the International Standard for Good Refurbishment Practices. The standard previously existed as a publicly available specification (PAS) prior to becoming an IEC standard. This standard describes and defines the process of refurbishment of used medical imaging equipment and applies to the restoration of used medical imaging equipment to a condition of safety and performance comparable to that of new medical imaging equipment. This refurbishment includes actions such as repair, rework, software/hardware updates, and the replacement of worn parts with original parts.⁸ We have not yet studied the status of introduction and acceptance of IEC 63077:2019 in the “APEC” member economies. This could be the subject for a Phase II Project.

2.2 DEFINITIONS: REFURBISHED, REMANUFACTURED AND USED/SECOND-HAND

In most sectors, the terms remanufacturing and refurbishing are often synonymous.⁹ For the medical device sector, however, there is an important distinction between the two terms as indicated below. Additionally, these terms can have different meanings in local economies or within specific market segments.

REMANUFACTURED

In the United States, the Food and Drug Administration (FDA) defines a remanufacturer of medical devices as “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications, or intended use.” Thus, the remanufacturer is deemed the same as a manufacturer and needs to meet the U.S. FDA Quality System Regulations.¹⁰

The U.S. International Trade Commission (USITC) defines remanufacturing as “an industrial process that restores end-of-life goods to original working condition or better,” and this is widely recognized across various industry sectors.¹¹

The USITC definition also appears in federal legislation and is used by other government agencies, including the Office of the United States Trade Representative (USTR), U.S. Customs and Border Protection (CBP), and the U.S. Federal Trade Commission (FTC). USITC indicates that most U.S. remanufacturers of medical imaging equipment identify themselves as refurbishers rather than remanufacturers based on the U.S. FDA definition of remanufacturer.¹²

Some economies refer to **remanufactured goods** as entirely or partially composed of recovered materials and: (a) have a similar life expectancy and perform the same as or similar to such goods when new, and (b) have a factory warranty similar to that applicable to such a good.¹³ This terminology and associated definition have been used in FTAs, such as in the CPTPP and USMCA.

REFURBISHED

The DITTA Good Refurbishment Practice (GRP) Working Group (WG) was established in February 2012 with a focus on promoting medical imaging equipment refurbishment by OEMs and to enable

market access of this equipment.¹⁴ DITTA has also promoted the International Electrotechnical Commission (IEC) 63077:2019 international standard that describes and defines the process of refurbishing used medical imaging equipment. IEC 63077:2019 defines refurbishment as a “process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and performance according to the specification of the manufacturer” (further description of this can be found upon review of IEC 63077).¹⁵

The ASEAN Medical Device Directive (AMDD), Article 2 Definition and Scope, (I), (q) also defines refurbished medical devices, and it is similar to the IEC 63077:2019 definition.¹⁶ The AMDD was signed by the 10 ASEAN member states in 2015. The intent is for all member states to incorporate it into law; however, the timeline of implementation has varied amongst the ASEAN economies.¹⁷ The AMDD defines a refurbished medical device as the following:

“A refurbished medical device means a medical device of which the whole or a part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device and which may have had the following work carried out on it:

- (i) Stripping into component parts or subassemblies;
- (ii) Checking their suitability of reuse;
- (iii) Replacement of components/sub-assemblies not suitable for reuse;
- (iv) Assembly of the reclaimed and/or replacement components/sub-assemblies;
- (v) Testing of the assembled device against either original or revised release criteria; or
- (vi) Identifying an assembled medical device as a refurbished medical device.”

USED AND SECOND-HAND

Used medical imaging equipment is medical imaging equipment that has been put into service.^{18, 19} Used medical equipment that is at the end of expected service life or that cannot be restored to at least its original safety and performance levels, including all mandatory safety updates, is not considered refurbished.

Another term that is similar to “used” and “as-is” is “second-hand equipment,” which refers to equipment that has been in service and is put into service again, usually at another location. Figure 2 shows that devices that are refurbished in accordance with IEC 63077, 2019²⁰ meet the same requirements as a new device. However, second-hand devices that do not comply with the IEC 63077,2019 standard are likely not to meet the same requirements as new devices.

Figure 2 Refurbished devices according to IEC PAS 63077 in comparison to new devices and 2nd hand devices (standard subsequently released as EN IEC 63077:2019)^{21,22}

NEW MEDICAL IMAGING DEVICES	REFURBISHED MEDICAL IMAGING DEVICES ACCORDING TO IEC 63077	SECOND-HAND MEDICAL IMAGING DEVICES REFURBISHED BY NON-OEMS OR SOLD NON-REFURBISHED BY DEALERS
OEM test instructions		Typically no
Declaration of Conformity (DoC) Issued	confirmed 1)	Typically no
CE - mark (e.g., in EU) Issued	confirmed 2)	Typically no
Post-market surveillance	3)	Typically no
QMS ISO 13485	4)	Typically no
Performance and safety test	5)	Typically no

Notes:

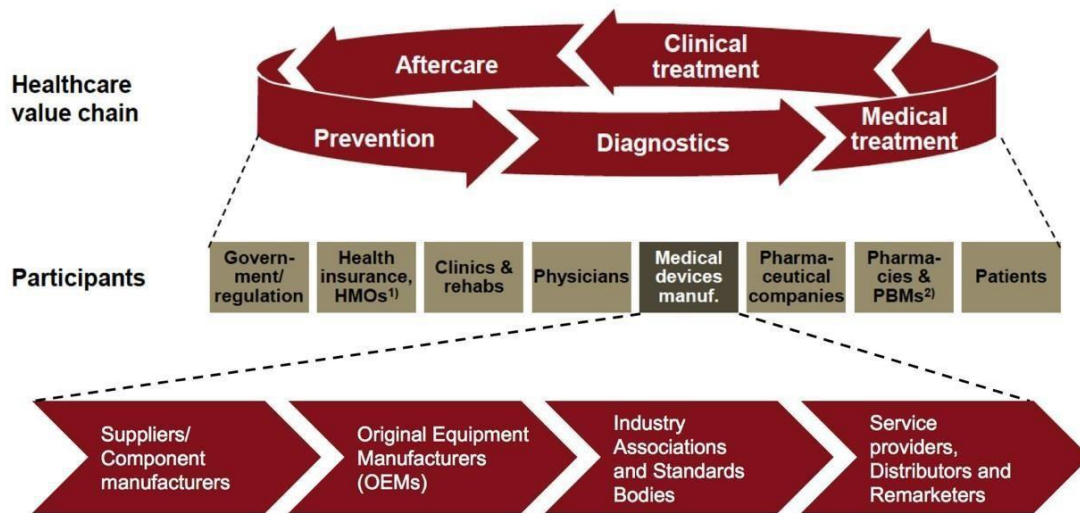
4.6. and 4.10 IEC 63077 / 2) This means that the manufacturer declares that the product meets all legal, regulatory, and technical requirements for CE marking / 3) 4.7. IEC 63077 / 4) 4.1 IEC 63077 / 5) 5.7 IEC 63077

2.3 OVERVIEW OF REFURBISHED MEDICAL DEVICE VALUE CHAIN

The global refurbished medical equipment market is highly concentrated; for example, the refurbished imaging equipment market is comprised of approximately 15 main companies worldwide. OEMs, such as GE Healthcare, Canon Medical Systems, Philips Healthcare, and Siemens Healthineers, have a significant market share of both new and refurbished medical imaging devices. The share of these companies in the diagnostic market is about 75 percent.

Within the refurbished medical device value chain, the entities involved are parts/components suppliers, OEMs, industry associations and standards bodies, and service providers, distributors, and remarketers (Figure 3).

Figure 3 Value Chain Structure²³



Both OEMs and non-OEMs refurbish medical devices; thus, there is competition between these two groups in terms of procuring and selling refurbished devices. OEMs have a resale advantage given their familiarity with their technologies and their infrastructure to service, finance, and remanufacture their own equipment.²⁴ The OEMs also have strong compliance expertise to product specifications that can ensure compliance with industry standards.²⁵ It is also important to note that OEMs must sometimes rely on contracted third parties to service their imaging devices as they may not have the capability and resources to manage this for their customers within all APEC economies. These OEMs maintain oversight over contracted third parties to ensure servicing has been performed properly

KEY MARKET ENVIRONMENT

3.1 CURRENT FINANCIAL CONSIDERATIONS: OVERVIEW OF GLOBAL MEDICAL DEVICE TRADE AND IMPACT OF COVID-19

The healthcare sector, along with the medical device industry, is expected to continue to grow. In 2018, ASEAN predicted that the new medical device market would attain a compound annual growth rate (CAGR) of almost 10 percent by 2020 and sustain it through 2024.^{26,27} Yet, the impact of the COVID-19 pandemic on each ASEAN economy and the associated trade challenges remain unclear within the overall global economic contraction. ²⁸ Even though supply chain challenges have negatively affected the refurbished medical devices market, the demand remains high and is growing. Since the start of the COVID-19 pandemic, global healthcare utilization shifted toward COVID-19 testing, treatment, research, and vaccination, and away from other services — including life-saving medical care. Demand for products to address the COVID-19 pandemic caused severe challenges in the medical product supply chain in 2020, as manufacturers struggled to produce and ship sufficient quantities of PPE, ventilators, extracorporeal membrane oxygenation (ECMO), and other supplies.

The economic impacts to the Asian economies in this report (Malaysia, Thailand, and Viet Nam) were severe. Economists downgraded Malaysia’s 2021 growth forecast in the range of 1 to 3 percent, and have regarded the economy as one of the most negatively impacted in Asia.²⁹ Thailand experienced a 5.4 to 6.4 percent contraction in Gross Domestic Product (GDP) as an economic consequence of the

pandemic in 2020.³⁰ Viet Nam experienced its slowest growth rate (1.8 percent) in more than three decades.^{31,32}

In 2020, healthcare systems experienced declines in revenue due to the decreased volume of services provided (aside from COVID-19 care). This has resulted in financial constraints in healthcare, which will necessitate health systems to evaluate their needs for costly equipment. Despite the desire to provide quality healthcare and further public health, hospitals may need to tighten spending regardless of the healthcare model in the member economies.

3.2 REFURBISHED MEDICAL DEVICE OPPORTUNITIES

Refurbished medical devices offer several potential benefits to APEC economies. As mentioned, the purchase and use of refurbished devices would reduce healthcare spending without compromising quality of healthcare delivery. Refurbished medical devices may even help to stretch healthcare budgets further. The market drivers and opportunities include reducing waste, conserving resources, and accessing the ongoing high-tech enhancements of medical devices that may not otherwise be accessible to patients who could substantially benefit from them.

Economies benefit from the lower cost of refurbished medical imaging equipment and parts, and refurbishing can extend the lifecycle of high-end medical imaging devices. Imaging scanners and diagnostic devices, such as CT scanners and MRI devices, are in high demand. By purchasing refurbished medical imaging devices, developing economies can shift investment to other viable areas.

As such, refurbished medical imaging devices would make a difference in the domestic supply of lifesaving healthcare equipment by offering greater choices to public and private healthcare providers, and providing a solution for economies experiencing shortages of medical equipment and continued increases in medical spending.

3.3 POTENTIAL CHALLENGES TO TRADE IN REFURBISHED MEDICAL DEVICES

Nonetheless, there are inherent potential challenges related to market access for refurbished medical imaging devices. Importation of these devices is heavily regulated and/or banned in several economies. While some APEC economies have indicated their support of the use of refurbished medical devices (e.g., remanufactured goods overall, such as through the APEC Pathfinder, CPTPP, and USMCA), many have not yet established the detailed regulations to effectively guide industry and healthcare institutions.

Contributing to the reluctance of some APEC economies to implement regulations for refurbished products is that the subsector is highly specialized, requiring niche expertise in the areas of regulatory affairs, quality, service, training, and operations. Implementation of refurbishment regulations requires a solid understanding of medical device requirements to ensure that refurbished medical devices will perform according to their intended use and remain safe and effective. As such, medical imaging equipment is a good place to start with these efforts as there is strong collaboration amongst OEMs, as evidenced by the development of refurbishment standards (IEC 63077:2019) for medical imaging devices. As mentioned above, the development and adoption of standards could be a strong focus for APEC consideration in future regional- and economy-level assistance initiatives. Additionally, healthcare institutions may be hesitant to purchase refurbished medical devices as a result of a perceived concern that there may be a risk to patient health and to the reputation of their institution. Thus, due to these

misconceptions, the benefits of refurbished devices may not be realized, hindering market growth for refurbished medical devices despite FTAs.

Therefore, one of the challenges is the overall perception of refurbished products as being inferior in quality, performance, durability, reliability, safety, and efficacy, which may impede the use of refurbished medical devices. Furthermore, refurbished medical devices are primarily imported and their refurbishment facilities are limited worldwide. Thus, the service, repair, and maintenance support for these products can be difficult to find and maintain in some economies that do not have these resources locally.³³ However, when the products are refurbished in accordance to IEC 63077, it is the responsibility of the refurbisher to ensure appropriate service in the economy where the product is being distributed.

REGIONAL/ECONOMY-LEVEL ANALYSIS

We conducted APEC economy-level snapshots for Malaysia, Thailand, the United States, and Viet Nam. These economies were chosen as examples of varying regulatory requirements for refurbished medical devices. From the industry perspective, it is important that Ministries of Health and/or other domestic ministries responsible for import and export of medical devices (depending on the economy) provide specific guidance regarding import requirements for refurbished devices.

Not all economies highlighted in this report have implemented regulatory requirements specific to the importation of refurbished medical imaging equipment within the value chain, although these economies have made commitments to support trade of remanufactured goods. The next step then is to establish regulations specific to refurbished medical devices. Once these regulations are in place, the economies will be able to implement the guidelines pertaining to the specific requirements for importing refurbished medical equipment (Figure 4). An economy will typically take these steps in order to fully execute on their commitments to support the trade of refurbished medical device products.

Figure 4a Status of FTA and Support in These Economies

ECONOMY	FTA	SUPPORT REMANUFACTURED GOODS
U.S.	USMCA	
MALAYSIA	CPTPP	
THAILAND	N/A	
VIET NAM	CPTPP, EU-Vietnam FTA	

Notes:

The current status of medical devices regulations in each economy and their specific requirements for importing refurbished medical equipment were analyzed (Figure 4b).

Figure 4b Levels of Refurbished Device Support and Restrictions in Select APEC Economies Highlighted in this Report

ECONOMY	MEDICAL DEVICE REGULATIONS	REFURBISHED MEDICAL DEVICE REGULATIONS	IMPORT OF REFURBISH MEDICAL DEVICE
U.S.		1	Yes, follow the current regulations ¹
MALAYSIA		2	Yes, follow the current regulations ²
THAILAND		3	Restricted ³
VIET NAM		4	Restricted ⁴

Notes:

– Yes; – No

1. In the USA, the FDA regulates the refurbishment of medical devices as a Service Activity³⁴

2. In Malaysia, refurbished medical devices are regulated as per the Circular Letter of the Medical Device Authority No. 1 Year 2016 (Revision 2)

3. In Thailand, no specific regulation for refurbished medical devices, and used medical equipment is on the list of prohibited imports. According to local industry representatives, it may be very difficult or unlikely to import refurbished medical equipment at this time.

4. In Viet Nam, used medical equipment is on the List of Prohibited Imports. According to local industry representatives, it is not possible to import refurbished medical equipment for commercial use. However, the economy is in the process of implementing the CPTPP and EU-Vietnam FTA with regards to the importation of remanufactured goods, including refurbished medical devices.

4.1 FOREIGN TRADE AGREEMENT COMMITMENTS

Remanufactured goods, including refurbished medical devices such as CT scanners and MRI equipment, have been addressed in various FTAs affecting APEC economies, such as CPTPP and USMCA. This examination is not meant to be an exhaustive legal/regulatory analysis, but rather to set the stage to examine how given APEC economies may be struggling to comply with international commitments, and where technical assistance, public-private dialogue, and training may be required.

The CPTPP was launched in 2019 to reduce trade barriers among 11 partner nations representing nearly 500 million consumers in the Asia-Pacific region.³⁵ All CPTPP members are APEC economies: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Viet Nam.

The CPTPP includes language regarding trade in remanufactured goods. Malaysia and Viet Nam have signed the CPTPP and, therefore, have committed to accepting refurbished medical equipment. However, Malaysia has not yet ratified the agreement while Viet Nam ratified the CPTPP on March 8, 2018. Thailand has not joined CPTPP and, therefore, is not bound to its commitments.

CPTPP includes a provision promoting trade in remanufactured goods by requiring that remanufactured goods not be subjected to any import prohibitions or restrictions that are applied to used goods. The CPTPP definition of remanufactured goods aligns with the objective of supporting the use of refurbished medical imaging equipment. In CPTPP, remanufactured goods are distinct from used goods in that they undergo significant processing beyond cleaning, repair, and maintenance, and are thus restored to a much higher level of functionality than a repaired or used good.³⁶

4.2 MALAYSIA

Malaysia regulates market access for refurbished medical imaging devices. Quantitative import restrictions are seldom imposed and only on a limited range of products. The Royal Malaysian Customs Department provides a listing of prohibited and restricted items.³⁷ Moreover, in Malaysia, medical devices require a license issued by the Ministry of Health (MOH) for importation or exportation.³⁸

In 2012, two key pieces of legislation were enacted that impact market access for refurbished medical imaging devices: Medical Device Authority 2012 (Act 738)³⁹ and Medical Device Act 2012 (Act 737)⁴⁰ with subsidiary regulation. Both Acts became effective in 2013, and key elements include:

- The role and responsibility of manufacturers, authorized representatives, distributors, and exporters,
- Product approval requirements as set by the ASEAN Common Submission Dossier Template (CSDT) for medical devices,
- Post-marketing alert systems according to the Annex of the AMDD,
- Mandatory information on labeling and instructions for use according to the Annex of the AMDD,
- Quality System Requirements for manufacturers (ISO 13485), and • Upcoming regulations in 2021 for Malaysia to further align with AMDD.

Although Malaysia has not yet ratified CPTPP and its commitments on remanufactured goods,⁴¹ the economy of Malaysia has a full set of refurbished medical device regulations. Basically, the regulations on new or refurbished medical equipment all implement the Malaysia Medical Device Act 737.⁴²

In January 2016, MDA issued a guidance document entitled “Good Refurbishment Practice of Medical Devices.”⁴³

- In September 2019, MDA issued a draft of the guidance “Notification of Refurbished Medical Device” and collected feedback on the draft.⁴⁴
- In September 2020, MDA issued Circular Letter No. 1 Year 2016 (Revision 2), Policy on Implementation and Enforcement under the Medical Device Act 2012 (Act 737) for Refurbishment of Medical Device.⁴⁵

These latest MDA regulations provide an outline of the model that the government will implement. According to a review of the ASEAN Trade Repository, there are no known procurement requirements precluding the purchase of refurbished medical devices, but the restrictions listed above do apply. The private sector has been especially active in investment in medical diagnostic and therapeutic equipment. Thus, there is potential for significant growth opportunities for refurbished medical equipment in Malaysia.

According to Malaysia’s Good Refurbishment Practice of Medical Device (GRPMD), Article 4.4 Refurbisher, there are two categories of refurbishers: 1) Manufacturer; or 2) Third-party Refurbisher. In Malaysia, the requirements regarding importation by a third party are clearly defined on the Circular Letter of the Medical Device Authority, No. 1 Year 2016 (Revision 2).

Malaysia allows the import of refurbished medical device provided by a third-party refurbisher, if they meet these five requirements:

- Obtain establishment license as a manufacturer,
- Complete registration,
- Comply with Good Refurbishment Practice for Medical Devices (GRPMD),
- Get conformity assessment by the Conformity Assessment Body (CAB), and
- Provide technical details for the medical device.⁴⁶

4.3 THAILAND

According to the U.S. Department of Commerce, Thailand has a “strong healthcare infrastructure, highly skilled medical professionals, and international standard medical services and has an economy known for improving local healthcare delivery.”⁴⁷ Improving local healthcare and a growing aging population demand an increased use of healthcare services and supplies. However, medical spending in Thailand must also be considered within the broader economic challenges resulting from the COVID-19 pandemic: Thailand experienced an economic contraction of 5.4 to 6.4 percent in 2020.⁴⁸

Per the Asian Harmonization Working Party/Global Harmonization Working Party (AHWP/GHWP) website, the Thai authority reported significant increases in manufacturing and imports of COVID-19 related products and one-time-use PPE in 2020. Thai imports of some of these products increased 50fold, and local production increased by roughly seven-fold.⁴⁹ Furthermore, while the importation of COVID-19 PPE increased, overall imports of medical devices decreased by approximately 25 percent. However, it is predicted that the medical device sector will grow by 8 to 10 percent in 2021.⁵⁰

It has been reported that, “among the ten ASEAN members, Thailand has the highest total value of imports and exports of medical devices. Seventy percent of the medical devices manufactured in Thailand are exported and the remaining 30 percent distributed for domestic uses.”⁵¹

In response to the effects of the COVID-19 pandemic on the healthcare industry, in April 2020, the Thai Board of Investment (BoI) implemented measures to accelerate investment in the medical care industry and provided a tax holiday on medical device purchases. More specifically, “Thailand’s reliance on medical devices imports, such as some raw materials for disposable devices and sophisticated medical devices such as electromechanical devices and hospital hardware, represent a great opportunity for [international] manufacturers of medical devices to substitute the imports with local manufacturing,” according to the Bangkok Post.⁵²

All of these factors indicate the potential for increased growth in the medical device industry in Thailand, but this assessment only pertains to new medical devices and not to refurbished diagnostic medical imaging equipment.⁵³ Since 2008, Thailand has been identified as an economy prohibiting the importation of used or refurbished medical equipment, although in 2021, Thailand’s customs website does not include used medical equipment on any list of restricted items.

The Thailand Health Authority published Thailand’s Medical Device Act (No. 2) B.E. 2562 (2019) regarding new medical devices.⁵⁴ The rationale for implementing this Act is to ensure that Thailand’s medical device control measures are consistent with the ASEAN Agreement on Medical Device Directive (AMDD).⁵⁵ On January 19, 2021, Thailand submitted their Instrument of Ratification to AMDD.⁵⁶

The key contents of the new Act include:

- Definition of medical device, accessory, manufacturer, listing person, among others.
- A CSDT will be implemented as required for product approval.
- Post-Marketing Alert Systems are necessary according to the Annex of the AMDD.
- Mandatory information required on labeling and Instructions for Use. For home use of the medical device, the Instructions for Use need to be in Thai language, and for professional use either Thai or English language is acceptable.
- The Minister of Health shall issue a Ministerial Regulation or Notification within two years from the date of the publication of this Act.⁵⁷

According to the current Thailand medical device regulations, there is no mention of refurbished medical devices. How the Medical Device Act (no. 2) B.E. 2562 (2019) will be applied to refurbished medical devices needs to be further investigated. This will help determine whether a third party can legally import a device, which was previously registered, in refurbished condition without the medical device being subjected to new safety inspections. It should also explain whether public health institutions can buy imported refurbished medical devices, i.e., whether there are public procurement regulations precluding the purchase of refurbished devices.

4.4 UNITED STATES

According to the Observatory of Economic Complexity (OEC) World, in 2019 the United States was the top exporter of medical instruments with an annual export of \$29.5 billion.⁵⁸ Moreover, 46 percent of refurbished medical imaging devices that are sold globally are sold in the United States⁵⁹ The U.S. FDA defines the service of refurbishment as the “repair and/or preventative or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that change the intended use of the device from its original purpose or change the safety or performance specifications.”⁶⁰

There are no technical regulations, service requirements, or other non-tariff measures (e.g., import licensing or customs procedures) that apply to refurbished medical equipment that do not apply to new medical equipment in the United States.

A third party can legally import a refurbished medical device that has already been registered within the United States and meets all of the U.S. FDA medical device requirements. The medical device would not be subjected to new safety inspections.

Furthermore, public health institutions can buy imported refurbished medical devices. There are no public procurement regulations precluding the purchase of refurbished devices.

4.5 VIET NAM

Viet Nam does not domestically manufacture medical imaging devices and, therefore, relies on imports. However, until recently, importation of refurbished medical devices was prohibited. In November 2018, the Viet Nam National Assembly ratified the CPTPP, which provided the first step toward an easier pathway for the importation of refurbished medical devices and opened their market potential.⁶¹

The Department of Medical Equipment and Construction (DMEC), Ministry of Health (MOH), is the regulatory authority for medical devices in Viet Nam. In order to consolidate the medical device regulations and facilitate the development of industry, MOH released an official dispatch no. 2271/BYT-TB-CT on March 31, 2021.⁶² This dispatch unified the three previous decrees:

- Decree 36/2016/ND-CP — Classification of Medical Devices, on-line publishing and registration, administrative procedures, and standard applicable to class A,
- Decree 169/2018/ND-CP — Renewal of medical device import permits of Class B, C, and D, improving on-line registration procedures, and
- Decree 03/2020/ND-CP — Roadmap to implement the CSDT Electronic Information portal in Vietnamese Publicize price of the medical device.

The Official Dispatch focused on clinical trials, Essential Principles for Safety and Efficiency of Medical Devices, and advertising.⁶³ Furthermore, Quality System Requirements for domestic medical device manufacturers include the ISO 13485 requirement for medical devices before January 1, 2020. Clinical Trial Evaluation is required, but if the medical device has been in circulation and granted Certificates for Free Sale by Australia, Canada, EU, Japan, and the United States, the clinical requirements can be exempted.⁶⁴

This Official Dispatch No. 2271/BYT-TB-CT did not include the topic of medical device refurbishment. Whether this regulation applies to refurbished medical devices needs further clarification, including regarding whether a third party can legally import a previously registered device in refurbished condition without the medical device being subjected to new safety inspections. The Official Dispatch should provide information about whether public health institutions can buy imported refurbished medical devices, i.e., whether there are public procurement regulations precluding the purchase of refurbished devices.

At the same time, Decree 69/2018/ND-CP, Article 5, Appendix I Section II, Point 4 (dd), prohibits the importation of used consumer goods, medical equipment and vehicles are prohibited from import.⁶⁵ However, Decision 2019/1997/QĐ-BKHCMNT states that the Ministry of Science and Technology must inspect and certify all imports of used and refurbished medical equipment. In practical terms, MOH accepts used equipment for donation purposes only.⁶⁶

RECOMMENDATIONS

As APEC economies continue to contend with the public health and economic effects of COVID-19, healthcare systems should be given the option to purchase refurbished medical devices, through regulations consistent with international trade agreements, such as CPTPP and USMCA, through relevant international standards such as IEC 63077:2019, and with regional arrangements such as the APEC Pathfinder on Remanufactured Goods. Refurbished medical devices, produced and serviced according to Good Refurbishment Practices, supply high quality, innovative and affordable technology.

Recommended future opportunities in APEC include:

- Continue the APEC Pathfinder initiatives and invite participation from more APEC economies.
- Support the widespread use of International Standard IEC 63077:2019 “Good Refurbishment Practices for Medical Imaging Equipment”⁶⁷ to harmonize terminology and requirements for refurbishment practices globally. A next step might be to identify which APEC economies have adopted IEC 63077.
- Offer technical assistance to APEC economies, as well as targeted APEC-wide workshops and trainings regarding refurbished medical devices in the medium- to long-term timeframe through the cooperation with the APEC Market Access Group (MAG), APEC Life Science Innovation Forum (LSIF), especially the Regulatory Harmonization Steering Committee (RHSC).
- With regard to specific APEC economies, Malaysia has issued a specific regulation for refurbished medical devices, and member economies may benefit from learning about Malaysia’s experience with its implementation. Additionally, the U.S. could be consulted to discuss how it treats refurbished medical devices.
- Member economies should consider updating some or all of the 2013 Remanufacturing Resources Guide,⁶⁸ focusing in particular on the status of each economy’s measures applicable to remanufactured goods, including refurbished medical devices.

Consequently, there are many areas on which to collaborate to pave the ground for future growth in market access for refurbished medical imaging devices in APEC economies. By extending the lifetime of medical devices, member economies can also save resources and energy costs that would have been devoted to new production, which contributes to the adoption of more circular economies. Through the APEC Pathfinder and specific discussions in other fora, APEC can play an important role in promoting the benefits of refurbished medical devices and remanufactured goods more broadly.

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