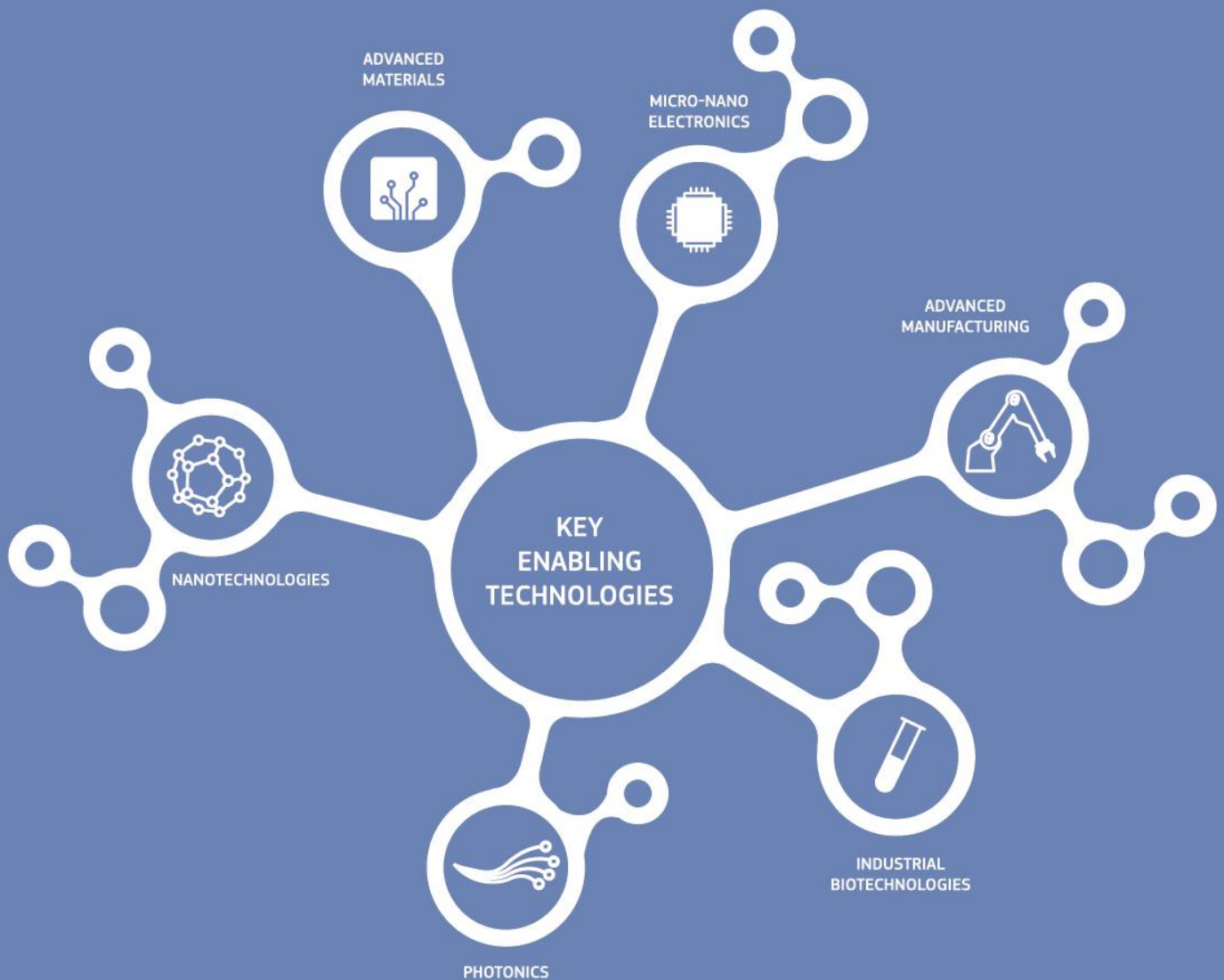




KETs OBSERVATORY PHASE II



REFURBISHMENT OF MEDICAL EQUIPMENT Report on promising KETs-based product nr. 4

Contract nr EASME/COSME/2015/026

The views expressed in this report, as well as the information included in it, do not necessarily reflect the opinion or position of the European Commission.

REFURBISHMENT OF MEDICAL EQUIPMENT

Report on promising KETs-based product nr. 4

KETs Observatory Phase II
Contract nr EASME/COSME/2015/026

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Executive summary

The current report aims to provide stakeholders with an analytical base helping to strengthen cross-regional cooperation mechanisms to boost the deployment of Key Enabling Technologies in Europe. The report specifically aims to highlight the value chain structure, key players and constraints for the domain of *refurbished medical equipment* in Europe. It also addresses the key strengths and potential of the EU regions, as well as promising business opportunities and key risks and challenges. Finally, the report elaborates on specific policy recommendations with both immediate focus and longer-term orientation.

In this report, we focus on the refurbished medical equipment market, and within that niche, specifically on capital imaging devices (such as CT scanners, MRI and other diagnostic imaging equipment) and less on single-use devices (such as scalpels, catheters, compression sleeves etc.). The refurbished medical equipment market contributes to grand societal challenges by reducing waste and conserving resources; increasing access to healthcare in markets with increasing healthcare cost pressure; and offering economic benefits from extending the lifecycle value of manufactured equipment and creating new jobs, growth and investment within the EU.

The demand and supply within Europe are reported to be steady. Stakeholders suggested that it would be highly challenging to support a Europe-only business case, as everything from parts and components to eventual resale destinations necessitates a global outlook. The global value chain for refurbished medical equipment is quite restricted in terms of access due to the niche expertise and stringent regulatory certifications required for such equipment. The involved value chain players include parts/components suppliers, original equipment manufacturers, industry associations and standards bodies, and service providers, distributors and remarketers.

Except for regional sales, distribution and service channels, most of the economic activity for refurbishment is currently concentrated in Western Europe. Improving market penetration for quality healthcare in Central and Eastern Europe may increase demand enough to also grow local ecosystems for this market. Even though the business case for refurbished systems within Europe is relatively strong, true economies of scale may only be realised if global shipments of used and refurbished equipment could be achieved. Currently, there are a few key regulations that are reported to hinder businesses from fully capitalising on this niche domain.

A major risk for Europe is increasing competition from emerging markets, developing new low-cost equipment, which is price-competitive with refurbished high-quality equipment. Promising opportunities for this domain would emerge if trading partners, Member States, business community, as well as citizens would be more educated on the Circular Economy paradigm of extending the lifetime of products while maintaining high quality. This requires business stakeholders to design products differently than typical linear business models. The EU funding to support the growth of the infrastructure required for circular economy initiatives would not only help the market for refurbished medical equipment, but would also broadly grow the business case for circular business models across multiple sectors.

1. Introduction

The current report has been developed in the context of the second phase of the KETs Observatory initiative. The KETs Observatory represents an online monitoring tool that aims to provide quantitative and qualitative information on the deployment of Key Enabling Technologies¹ (hereafter “KETs”) both within the EU-28 and in comparison with other world regions. Specifically, the KETs Observatory represents a practical tool for the elaboration and implementation of Smart Specialisation Strategies in the EU regions.

1.1 Background

A key challenge for the EU competitiveness policy is to enable European industry to move to the higher end of the value chain and position itself on a competitive path that rests on more innovative and complex products. For many KETs, this implies a focus on more integrated technologies with the potential of connecting several KETs.

To this end, one of the key tasks of the KETs Observatory implies identifying and describing “promising KETs-based products” and their value chains, and recommending specific policy actions to help the EU industry stay ahead of global competition. Promising KETs-based products here can be defined as emerging or fast-growing KETs-based products with a strong potential to enhance manufacturing capacities in Europe. Such products correspond to KETs areas where Europe has the potential to maintain or establish global industrial leadership - leading to potentially significant impacts in terms of growth and jobs.

1.2 Objectives of this report

In the context of the second phase of the KETs Observatory, in total, 12 promising KETs-based products have been selected for an in-depth analysis of their value chain, the associated EU competitive position and the corresponding policy implications. The selection of the topics stems from a bottom-up approach based on active engagement of regional, national and EU stakeholders through the S3 Platform for Industrial Modernisation².

This report presents the results of the abovementioned in-depth analysis for one of the selected top-priority topics, namely **refurbishment of medical equipment**. The analysis is based on desk-research and in-depth interviews with key stakeholders. The report aims to provide relevant stakeholders with an analytical base helping to establish or strengthen cross-regional cooperation mechanisms to boost the deployment of KETs in Europe.

¹ Namely Nanotechnology, Micro-/Nanoelectronics, Photonics, Industrial Biotechnology, Advanced Materials and Advanced Manufacturing Technologies

² <http://s3platform.jrc.ec.europa.eu/industrial-modernisation>

1.3 Target audience

The report aims to provide key market insights for refurbishment of medical equipment and identify key directions for action in order to maintain Europe's competitive position on the global market. The report specifically targets the EU, national and regional policy makers and business stakeholders who are currently involved in or consider engaging in cross-regional cooperation mechanisms. The report may also be relevant for other key stakeholder groups including academia, as well as different support structures such as cluster organisations, industry associations and funding providers.

2. Key product facts

In the current section, we provide a brief introduction to *refurbished medical equipment*. We also elaborate on the market potential and the importance of this product for the EU competitiveness.

2.1 Introduction to the product

Medical devices are a key part of modern healthcare, and medical equipment manufacturers are crucial players within the healthcare system value chain, working especially closely with universities, research institutions, clinics, hospitals and pharmaceutical companies.

Medical devices generally fall under three categories: diagnostics, therapy and aids³. Diagnostics equipment consists of products supporting the data collection for medical procedures such as imaging equipment, *in vitro* diagnostics and disposable monitoring equipment. Therapy equipment typically implies products that support clinicians in performing medical procedures such as surgical robots, general clinical equipment (like endoscopes), operating room equipment, specialised ophthalmic equipment, radiation therapy devices and dental surgery equipment. Aids are products that support patients either temporarily or permanently, including mobility aids, clinical equipment (like dialysis machines), ear-nose-throat aids, administrative aids (like inhalers and syringes) and *in vivo* implants (like pacemakers or bone substitutes).

In this report, we focus on the refurbished medical equipment market, and within that niche, specifically on capital imaging devices (such as CT scanners, MRI and other diagnostic imaging equipment) and less on single-use devices (such as scalpels, catheters, compression sleeves etc.). Typically, diagnostic imaging equipment creates visual representations of the internal organs of the body to help in medical intervention and clinical analysis. Not only can this equipment improve diagnosis of conditions like cancer, Alzheimer's and other diseases, it also helps reduce the need for more invasive procedures. From a legislative perspective, this category of devices would be covered by Directives on medical devices and in-vitro diagnostics. However, stakeholders mentioned that this only reflects the status quo for the current applicable legislation; for instance, the EU Medical Device Regulation (MDR) and the EU In Vitro Diagnostic Regulation (IVDR) are in their transition phase right now and will apply from 2020 and 2022 respectively.

From a regulatory compliance perspective, the EU MDR defines the terms “fully refurbishing” and “reprocessing” as follows⁴. “Fully refurbishing”, for the purposes of the definition of the manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device. “Reprocessing” means a process carried

³ Produced by PwC/Strategy& for internal market intelligence, “The MedTech Greenhorn Guide”, Published in Sep 2014

⁴ EUR-Lex, Official Journal of the European Union L117, Published May 2017, Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC>

out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization and related procedures, as well as testing and restoring the technical and functional safety of the used device. Typically the conditions for “reprocessing” only apply for single-use devices, and thus not applicable to medical imaging equipment.

Often in the industry, the terms “refurbishing”, “reprocessing”, “remanufacturing” and “reconditioning” are used interchangeably⁵. According to global DITTA and the European COCIR (trade associations for the diagnostic imaging, healthcare IT and radiation therapy market), refurbishment is defined as “a systematic process that ensures safety and effectiveness of the medical equipment without significantly changing the equipment’s or system’s performance, safety specifications and/or changing intended use as in its original registration”⁶. “Reconditioning” typically comprises of cosmetic maintenance with replacement of worn parts with no disassembly involved. “Reprocessing” and “remanufacturing” may both refer to the same process, where actions taken significantly change the device’s performance, safety specifications or intended use⁷. Typically, this may include disassembly of the devices to replace major components. Hardware or software may also be upgraded, followed by extensive testing, quality assurance and (as required) re-submission for regulatory approval. Refurbished systems are also distinct from “pre-owned” equipment in that the latter are re-sold as-is from one end-user to another without any substantial quality checks or parts replacement, whereas the former are re-serviced thoroughly and ultimately offered to end-users with warranty and extended support.

As a rule, OEMs in the space of capital medical equipment neither perform “fully refurbishing” nor “reprocessing” as defined in the EU MDR. Rather, they refurbish their medical imaging devices according to IEC 63077 requirements⁸ which 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 effectiveness comparable to when new. According to stakeholders, refurbishment can include activities such as repair, rework, replacement of worn parts and update of software/hardware but shall not include activities that result in regulatory submissions, such as processing that changes the intended use of the device or alter its safety and performance. In this sense, the EU MDR definitions of “fully refurbishing” and “reprocessing” do not seem to apply to the kind of refurbishing being delivered by OEMs.

A typical refurbishment process includes the following steps⁹. Refurbished systems are brought to the original specifications comparable to brand-new equipment by either OEMs or non-OEM refurbishers. First, used devices are carefully selected based on their condition, service history or age. They are properly de-installed by accredited

⁵ EUR-Lex, Official Journal of the European Union L117, Published May 2017, Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC>

⁶ COCIR, “Good Refurbishment Practice for Medical Imaging Equipment”, Published in Jan 2015, Available at: https://issuu.com/cocir/docs/14021.dit.refurbishment_brochure_we

⁷ COCIR, “Good Refurbishment Practice for Medical Imaging Equipment”, Published in Jan 2015, Available at: https://issuu.com/cocir/docs/14021.dit.refurbishment_brochure_we

⁸ IEC, “Good refurbishment practices for medical imaging equipment”, Published in Nov 2016, Available at: <https://webstore.iec.ch/publication/26210>

⁹ Based on stakeholder interviews

personnel and transported to refurbishment facilities, typically at OEMs themselves. The devices are then serviced thoroughly, which includes disinfection, cleaning, painting, replacement of worn parts, software updates and quality testing. OEMs avoid significant modifications that might trigger the need for recertification¹⁰. On the other hand, if systems are sourced from outside the EU, refurbished and then sold within the EU, then they are required to fulfil the most recent regulatory requirements. The system is then sold at a substantially lower price compared to new equipment. When a buyer confirms purchase of the refurbished system, it is transported and installed at the client's location, with a standard system performance check just as with any new system. OEMs typically provide a service warranty to end-users for refurbished equipment, comparable to new equipment.

2.2 Relevance to grand societal challenges

The refurbished medical equipment market solves grand societal challenges in three main ways: (a) by reducing waste and conserving resources; (b) by increasing access to healthcare in markets with increasing healthcare cost pressures; and (c) by generating economic benefits from extending the lifecycle value of manufactured equipment and creating new jobs, growth and investment within the EU.

The humanity faces a challenge of achieving high levels of development while dealing with resource scarcity. The Circular Economy movement is an initiative encouraging business models that replace the linear “take, make, throw” paradigm with a cradle-to-cradle paradigm that is holistic, systemic and ultimately minimises waste throughput¹¹. Refurbished medical equipment can be placed within this context, as it contributes to creating access to quality healthcare and growing the economy while conserving resources.

2.3 Market potential

The refurbished medical equipment market has a high potential due to low production and material cost, contribution to containing hospital costs and high growth potential.

The global Medical Technology (MedTech) market is expected to grow by a CAGR of ca. 7% until 2018 to reach a volume of 380 billion EUR, of which Diagnostic Imaging is the largest segment worth ca. 100 billion EUR¹². According to COCIR, around 95% of medical companies in Europe are SMEs employing less than 250 people¹³. In 2015, the refurbished diagnostic imaging equipment accounted for 75.5% of the global

¹⁰ Only fully refurbished products are to be considered as new so that the person that places on the market a fully refurbished products assumes the obligation of a manufacturer. For products that are already placed on the market and that are subject to operations (e.g. repair and maintenance) which do not fall under the category of “full refurbishment” and which do not entail any significant change of the safety, performance and intended purpose of the original equipment (including the assignment of a new lifetime to the device), a new conformity assessment is generally not required.

¹¹ Ellen Macarthur Foundation, “What is a circular economy?”, Last accessed Sep 2017, Available at: <https://www.ellenmacarthurfoundation.org/circular-economy>

¹² Technavio, “Global Refurbished Medical Devices Market 2016-2020”, published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

¹³ COCIR, “Our Industry”, Accessed Sep 2017, Available at: <http://www.cocir.org/our-industry.html>

demand for refurbished medical devices. By 2020, the global refurbished medical devices market alone is estimated to be worth 8 billion EUR with a market growth rate of 8.31%. The EMEA market share at that time is estimated to be about 21%, worth about 1.7 billion EUR¹⁴.

The healthcare sector is increasingly facing heavy cost pressures¹⁵. Hospitals (as primary end-users of capital medical equipment) become increasingly cost-conscious because the economic downturn and increasing cost burden in healthcare systems impacts the available budget for healthcare in general, both for public and private actors. Moreover, increasing price transparency due to the professionalisation of sourcing, and consolidation of market share on demand-side gives customers more bargaining power. In some countries, reimbursements for medical procedures are also decreasing, introducing cost pressures from the patient side¹⁶. These cost-saving pressures not only affect the demand for medical devices but also the characteristics of these devices. For example, customers may prefer standard products over premium products, OPEX for maintenance over innovation, and preference for refurbished systems over high-margin new devices¹⁷. From an end-user's point of view, refurbished equipment is an attractive choice, as it provides good functionality at low cost and with a substantial warranty period. At the same time, there still are some end-user groups that value new over the perceived lower quality and innovativeness of pre-owned equipment¹⁸.

Finally, there is a growing demand for refurbished capital medical equipment in the emerging markets, evidenced by increasing number of diagnostic imaging procedures carried out in recent years. As of 2015, the demand in the Asia-Pacific region was only 17% of global market, but the estimated CAGR for the region is 8.59% between 2016-2020, much higher than the global CAGR of 7.49% for the same period¹⁹. As demand for high standard healthcare grows, the market penetration is expected to continue with more manufacturing plants and distribution channels across Asia-Pacific countries.

2.4 Importance for the EU competitiveness

The overall medical imaging market share of EMEA²⁰ (not just refurbished systems) was 32.55% in 2016, with a CAGR of 3.75% between 2016-2021²¹. By 2021, this

¹⁴ Technavio, "Global Refurbished Medical Devices Market 2016-2020", published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

¹⁵ Based on PwC/Strategy& internal market intelligence, Published Sep 2014

¹⁶ Technavio, "Global Refurbished Medical Devices Market 2016-2020", published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

¹⁷ *Ibid.*

¹⁸ Based on stakeholder interviews

¹⁹ Technavio, "Global Refurbished Medical Devices Market 2016-2020", published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

²⁰ Europe, Middle East and Africa

²¹ Technavio, "Global Medical Imaging Market 2017-2021", Published Jan 2017, Available at <https://www.technavio.com/report/global-patient-monitoring-devices-global-medical-imaging-market-2017-2021>

market share is estimated to be worth more than 10 billion EUR²². Even though some areas in Europe are showing signs of market saturation, other countries still have plenty of room for growth²³. These numbers suggest that there is a continued high demand for new systems, and a promising supply of refurbished systems in the coming years.

Moreover as of 2015, the EMEA region was estimated to have 22% of the global refurbished medical devices market with a CAGR of 6.55% between 2015-2020²⁴. This suggests a market cap of about 1.7 billion EUR by 2020. Again, these numbers suggest a steady demand for refurbished systems that is predicted to grow in the years to come. In addition, the rapidly growing demand from APAC region, discussed previously, is also a key driver for the EU-based OEMs and brokers to sell refurbished equipment.

The following factors are reported to influence the future of global refurbished medical equipment in the coming years (presented in order of high impact to low impact)²⁵:

- Increased adoption of low-cost refurbished equipment due to cost pressures;
- Negative sentiments towards pre-owned medical equipment in general;
- High demand from developing countries;
- Concerns regarding quality, safety and efficacy;
- Increasing privatisation in healthcare sector;
- Decreasing reimbursements for medical procedures;
- Increase in M&A in the MedTech domain;
- Stringent purchasing policies, especially in the public sector;
- Increased sales through online marketing;
- Increase in adoption of eco-friendly practices;
- Availability of pre-owned devices and customer interest to retain (parts of) original investment when replacing a device with a new device.
- A growing trend in healthcare (as in other industries) is to increase access while decreasing costs by more efficiently redistributing under-utilised capacity (otherwise known as uberisation).

²² Technavio, “Global Medical Imaging Market 2017-2021”, Published Jan 2017, Available at <https://www.technavio.com/report/global-patient-monitoring-devices-global-medical-imaging-market-2017-2021>

²³ Based on stakeholder interviews

²⁴ Technavio, “Global Refurbished Medical Devices Market 2016-2020”, Published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

²⁵ *Ibid.*

3. Value chain analysis

The current section addresses the value chain structure, key players, as well as the key identified constraints. While the demand and supply within Europe are reported to be steady, stakeholders suggested that it would be highly challenging to support a Europe-only business case, as everything from parts and components to eventual resale destinations necessitates a global outlook²⁶. The global value chain for refurbished medical equipment is quite restricted in terms of access due to the niche expertise and stringent regulatory certifications required for such equipment. This report will focus on the existing value chain within Europe and the implications for European business growth. This value chain can be considered already well-established, yet with a high growth potential.

3.1 Value chain structure

As outlined above, this report focuses on capital medical equipment (such as X-ray, CT scanners, MRI machines etc.) and not on single-use devices (such as scalpels, catheters etc.). Within this domain, there are mainly four kinds of players involved (see Figure 3-1), namely: (1) parts/components suppliers, (2) original equipment manufacturers (OEMs), (3) industry associations and standards bodies, and (4) service providers, distributors (this includes logistics players) and remarketers.

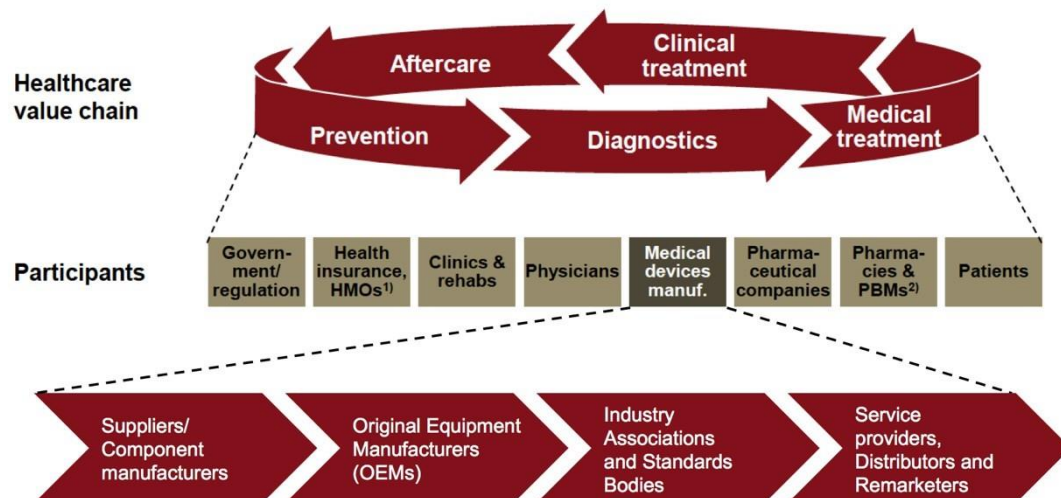


Figure 3-1 Value chain model for refurbished capital medical equipment (source: PwC²⁷; {1} HMO is an abbreviation of Health Maintenance Organisation; {2} PBM is an abbreviation of Pharmacy Benefits Management)

Figure 3-2 illustrates the value chain structure for medical devices, and specifically the players involved in the steps from reacquisition of use equipment to reselling and

²⁶ Based on stakeholder interviews

²⁷ *Ibid.*

servicing refurbished systems. It encompasses three dimensions: (1) value adding activities, (2) supply chain, and (3) the supporting environment.

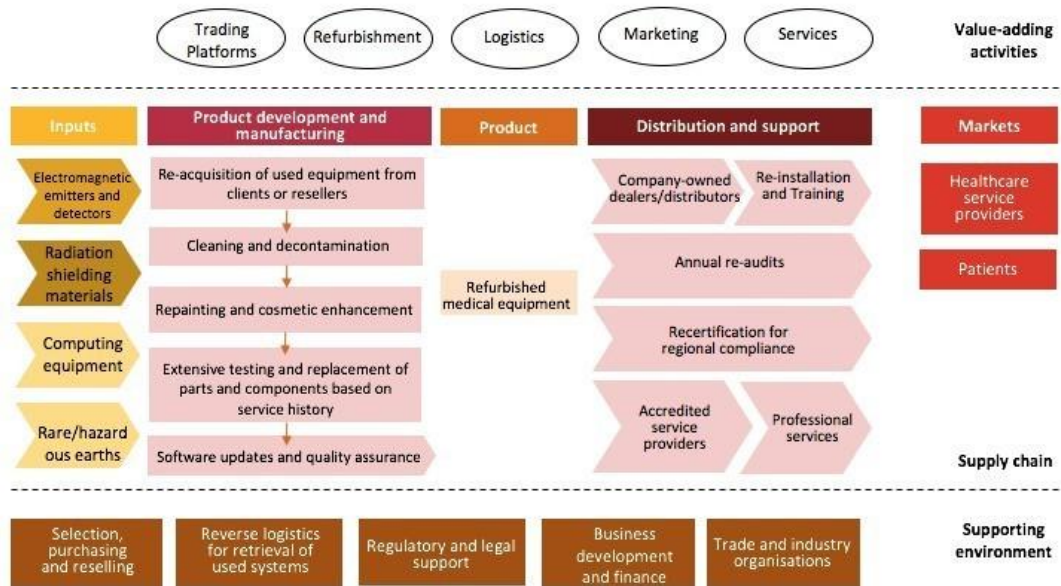


Figure 3-2 Value chain structure of the refurbished medical equipment market²⁸

Notably, the refurbished medical equipment market is unique in its structure and operations. For example, in the first dimension of value-adding activities, the refurbished medical equipment market does not feature R&D or design, for obvious reasons, compared to most other emerging products analysed in the context of the KETs Observatory initiative.

On the other hand, innovation in this niche domain of capital medical equipment is not always incremental or linear, like consumer technologies. Rather, user-specific needs – from research institutions, university hospitals, pharmaceutical companies etc. - are accommodated via new functionalities²⁹. As such, not all new functionalities are necessary relevant for all user groups of certain equipment³⁰. This has high impact on the competition and pace of innovation within the industry, as OEMs are constantly improving their equipment along slightly different roadmaps based on user needs and feedback. Moreover, this insight is of high relevance for the refurbished medical equipment, as even buyers of used equipment have a variety of functionalities and price points to choose from.

Similarly, in the second dimension of supply chain, some specific inputs have been identified. However, these are optional and minimal in most cases of refurbishment, being required only when existing parts within the used system are too degraded for safe and effective use, and there are no other spare parts readily available to exchange with.

²⁸ Based on stakeholder interviews

²⁹ *Ibid.*

³⁰ *Ibid.*

Moreover, end-users such as hospitals, imaging clinics and patients are identified as market demand drivers. They are sensitive to factors like price and features rather than the distinction between new or refurbished, especially considering that refurbished equipment have similar functionality to new equipment.

Given the highly specialised hardware and software that goes into these devices, and the high-pressure environment of the healthcare system, it is observed that the refurbishment aspect of the medical equipment market works relatively straightforward compared to the development curve of new medical equipment. However, new equipment continues to be developed in the global medical equipment domain, eventually entering the refurbished market. As such, it is worthwhile to monitor also the adjacent industries that influence the market in the development of new equipment as well.

Figure 3-3 shows the multiple industries that converge to develop medical technologies in general (henceforth referred to as MedTech), as well as examples of companies that are part of these industries.

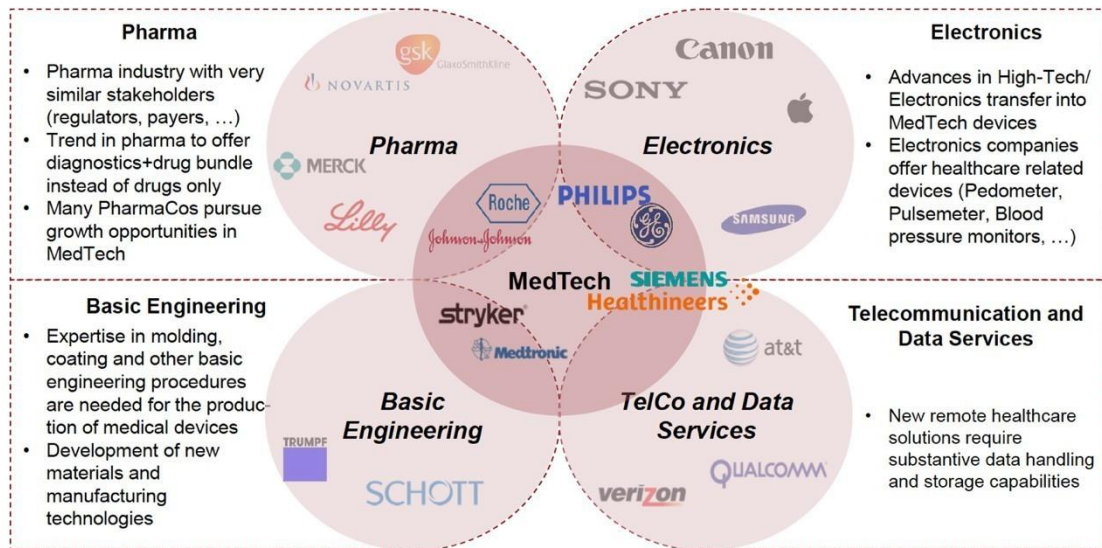


Figure 3-3 MedTech and its adjacent industries³¹

In the future, as trends like connected healthcare and preventative healthcare become more common, regulators and manufacturers would also need to work with players in the telco and data services domains. Moreover, to ensure long-life support for refurbished equipment, regulators and industry players need to work with basic engineering companies to ensure a steady supply of vital parts and components. Industry associations like COCIR are already involved in bringing together adjacent industry players such as telecom operators and healthcare IT companies to develop digital health solutions³².

³¹ Based on PwC/Strategy& market intelligence, Published Sep 2014

³² COCIR, "Our Industry", Accessed Sep 2017, Available at: <http://www.cocir.org/our-industry.html>

3.2 Key players

The global refurbished medical equipment market is highly rarified with only 15 main players globally, with several large (tier 1) companies, complemented by a few medium (tier 2) and small-sized (tier 3) companies³³. Specific types of key players include:

- **OEMs (Original Equipment Manufacturers):** the market share of tier 1 companies like GE Healthcare, Toshiba Medical Systems, Philips Healthcare and Siemens Healthineers in the diagnostic market is about 75%³⁴. All four companies have a high presence in the EMEA market for both new and refurbished systems.
- **Parts and components suppliers:** although the tier 1 players manufacture many of their own components, there are still some parts that need to be sourced externally and in some cases globally³⁵. As such, these tier 2/3 players are also part of the value chain.
- **Service providers, distributors and remarketers:** there is a free market dynamic to the purchasing, (re)servicing and rental/resale of capital medical equipment³⁶. As such, there are many tier 2/3 brokers and dealers in the market who offer these services, who have expertise in de-installation and logistics along with skilled installation, training and servicing capabilities.
 - OEMs and non-OEM refurbishers may compete in procuring and selling used devices, where OEMs have the resale advantage of deep expertise and high regulatory compliance standards, and the latter gain resale advantage through cheaper pricing.
 - In general, for both new and used equipment, OEMs rely heavily on their direct salesforce and/or distribution partners in the regions they operate in³⁷.
 - The salesforce for diagnostic equipment is relatively traditional, with interpersonal calls and manual explanations and sales pitches for equipment and product functionalities. It is possible as the products are expensive and demand volume is manageable³⁸. OEM refurbishers even provide standard warranty on refurbished products.
- **Industry associations:** Multiple OEMs are part of industry associations like COCIR and DITTA, which coordinate industry responses to regulatory, technical, environmental standardisation and legal issues regionally and internationally³⁹. Specialised trade associations like IAMERS also exist to

³³ Technavio, “Global Refurbished Medical Devices Market 2016-2020”, Published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

³⁴ Based on PwC/Strategy& internal market intelligence, Published Sep 2014

³⁵ Based on stakeholder interviews

³⁶ *Ibid.*

³⁷ *Ibid.*

³⁸ *Ibid.*

³⁹ COCIR, “About COCIR”, Accessed Sep 2017, Available at: <http://www.cocir.org/about-cocir.html>

represent companies selling and servicing pre-owned/refurbished medical equipment⁴⁰.

The following table (Table 3-1) illustrates some of the representative players in this value chain. Since the market is necessarily a global one, most tier 1 companies (typically OEMs) are international, and many tier 2/3 companies tend to be broker platforms rather than carrying out intensive remanufacturing. The list is not to be considered exhaustive.

⁴⁰ IAMERS, "About IAMERS", Accessed Sep 2017, Available at: <http://www.iamers.org/about-iamers/>

Table 3-1: Mapping of key market players⁴¹

| Organisation types/Value-adding activities | Production | Logistics | Marketing | Services |
|---|--|--|-----------|----------|
| Parts and components suppliers | PrimaXInternational(France) Balteau NDT (Belgium) BARCO (Belgium) | | | |
| Original equipment manufacturers (OEMs) | Royal Philips Healthcare (Netherlands) Siemens Healthineers (Germany) General Electric (United Kingdom) Toshiba Healthcare Europe (Netherlands) | | | |
| Service providers, distributors and marketers | | Agito Medical (Denmark) LBN Medical (Denmark) PROMED (Germany) DotMED.com Inc (United States) | | |
| Industry associations | COCIR (Belgium, EU), DITTA (Global), IAMERS (United States) | | | |

Below we illustrate typical relationships between players in this domain.

In the case of the larger tier 1 players (with >60% of market share), almost all roles in the value chain may be represented within a single company. For example, Royal Philips Healthcare manufactures many of its own components as well as equipment themselves. Philips is also part of multiple industry associations (such as DITTA and COCIR) to address regulatory issues that the industry faces. These associations are also performing voluntary self-regulation, such as publishing good refurbishment standards⁴². In general, OEMs like Philips perform direct sales and have long-term service contracts with clients such as hospitals and imaging clinics, performing yearly maintenance checks and servicing of equipment/parts for clients when necessary.

Typically, clients will retire their medical equipment, even if it is in working condition, in due time. According to stakeholders, this timing varies per equipment but generally average between 5-7 years⁴³. The reasons could be a desire to upgrade to the latest equipment, high consumer expectations, or even regulatory implications⁴⁴. Philips then performs reverse logistics for refurbishment when possible, offering to buyback, de-install, transport, service and finally resell medical equipment into the market⁴⁵.

European organisations like CEN and CENELEC may also be involved in the process from time to time to ensure remanufactured devices meet safety and minimum performance criteria.

⁴¹ The list of organisations presented in this table should not be considered exhaustive. It is rather an illustrative representation of organisations currently active in the value chain of refurbished medical equipment in Europe

⁴² COCIR, “Good Refurbishment Practice”, Accessed in Sep 2017, Available at: <http://www.cocir.org/initiatives/good-refurbishment-practice.html>

⁴³ Based on stakeholder interviews

⁴⁴ According to stakeholders, this sometimes manifests in the form of “discriminative” reimbursement policies where amounts returned are lesser if diagnostic equipment is older than a pre-defined number of years.

⁴⁵ *Ibid.*

In the case of tier 2/3 players, they are usually broker platforms that purchase entire used systems and/or important parts from multiple generations of product. Some companies may specialise in the machines and parts of specific OEMs, while others may collect all kinds of used machines available in the market. Some of these companies have accreditation and expertise to remanufacture and replace parts, whereas others simply buy and sell the products with relatively little intervention due to a couple of barriers.

Firstly, every OEM builds machines to specification with certain proprietary software⁴⁶. Given the high-technology nature of these machines, it becomes harder for external parties to service such “black box” systems. Even if specialised engineers would be intimately knowledgeable with the software and systems of individual OEMs, it is much harder to assemble a team of engineers who are similarly knowledgeable about all machines by all OEMs. Moreover, the more work put into a used machine by a broker, the higher the liability of that broker if problems arise among clients⁴⁷.

Typically, these brokers provide the platforms where sellers of used equipment can put up their systems for sale, or they buy available systems/parts and keep them in warehouses. Similarly, interested buyers of used medical equipment can browse these platforms for available units or make special requests for specific units. These middleman companies may also provide support with proper de-installation, quality testing and assurance, re-installation, re-certification, personnel training and warranty/insurance schemes for used medical equipment.

3.3 Key constraints

Several key constraints have been identified in the value chain for the refurbished medical equipment.

Stringent standards and approval mechanisms

Approval authorities in the EU and the United States (namely, the CE system and the FDA) are responsible for determining whether medical equipment can be sold in the market or not. In the EU, the CE system requires that all medical devices have to meet requirements set in the relevant applicable legislation to get the CE mark, with an emphasis on safety, effectiveness and efficiency depending on the class of devices. Moreover, the equipment is subject to surveillance audits annually and re-certification once in 5 years.

This is a potential bottleneck in the value chain if the goal is to maximise healthcare access. For example, in October 2017, Duke University researchers demonstrated how a 10 USD sensor from a typical smartphone could turn existing 2D ultrasound machines into 3D imaging devices – and this implies significant cost-savings because the latter is five times costlier than the former⁴⁸. In the current legislative framework, it

⁴⁶ Based on stakeholder interviews

⁴⁷ *Ibid.*

⁴⁸ ScienceDaily, “How a \$10 microchip turns 2-D ultrasound machines into 3-D imaging devices”, Published Oct 2017, Available at: <https://www.sciencedaily.com/releases/2017/10/171031111531.htm>

is unclear how these retrofit cost-savings can be preserved given the long and stringent approval process for “fully refurbishing” equipment. In the case of simple refurbishing, for OEMs in the refurbished medical equipment domain, compliance to such requirements is not reported to be a considerable challenge. However, for local refurbishers in regional ecosystems, these procedures become increasingly costly.

The lack of compatibility between FDA approvals and CE certification creates uncertainty among stakeholders⁴⁹. The quality standards are thus not transparent to end-users either, contributing to some of the mistrust of used equipment compared to new equipment with regards to quality, safety and efficacy⁵⁰.

This highlights an important corollary for growing the circular economy: educating consumers on its benefits and definitions. Consumers who are not aware of what exactly “refurbished” means may reject such devices even if they provide the same functionality and quality as a newer more expensive device.

Increasing regulatory hurdles and slow reforms

The purchasing, re-servicing and reselling of used medical equipment is part of a circular economy initiative, not a waste management activity. However, some stakeholders reported that regulations like the EU Directive on Waste Electrical and Electronic Equipment (WEEE) wanted to qualify pre-owned medical equipment as waste – especially when the devices were originally sold in non-EU markets and are being shipped back into the EU for refurbishment – and thus impose certain regulations which hamper resale within the EU⁵¹. Similarly, the Medical Device Directive also is reported to restrict sourcing opportunities for this market. On the other hand, from a regulator’s perspective, requiring the relevant certification procedures for resale within the EU of devices that have first been placed on the market in non-EU markets is a common principle to all product-related legislations, as per the Blue Guide on the internal market⁵².

Global market access and trade barriers

As multiple stakeholders mentioned, this market is only truly viable as a global market due to the uncertainty of variable supply and demand⁵³. Not every used system can be refurbished and resold, depending on variables like the working conditions of the product to the availability of parts for older models. Moreover, even if viable systems are available for reacquisition and refurbishing, there is not always a seller lined up, introducing quite some uncertainty to the business case. As such, it is hard to pin down

⁴⁹ BSI group, “Top Ten CE marking issues”, Published 2015, Available at: <https://www.bsigroup.com/meddev/LocalFiles/en-GB/Events/UK-Consultants-Day-2015/BSI-md-consultants-day-top-10-CE-marking-issues-presentation-UK-EN.pdf>

⁵⁰ Technavio, “Global Refurbished Medical Devices Market 2016-2020”, Published Sep 2016, Available at: <https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-global-refurbished-medical-devices-market-2016>

⁵¹ Based on stakeholder interviews

⁵² European Commission, “The Blue Guide on the implementation of EU product rules 2016”, Published Jul 2016, Available at: <http://ec.europa.eu/DocsRoom/documents/18027/>

⁵³ *Ibid.*

any one player as Europe-only. Moreover, any restrictions to global trading of equipment, services or parts significantly hampers the business potential in this market.

Several stakeholders mentioned regulations such as EU Directive on Restrictions of Hazardous Substances (RoHS) significantly limit the shipment of pre-used equipment depending on whether they were first placed on the market within the EU or overseas. Stakeholders mentioned that they witnessed more than a 30% decline in the European market once RoHS was implemented⁵⁴.

Similarly, regulations such as the Technical Guidance on Transboundary Movements of E-waste under the Basel Convention limits the shipment of refurbished medical equipment (again characterised as waste) from OECD to non-OECD regions and vice versa.

Finally, trade restrictions due to protectionist policies from certain markets significantly hamper the potential market for refurbished medical equipment. For example, imports are highly restricted in Brazil, China, Turkey and South Africa among others. Some stakeholders feel that this is unjustifiable from a quality perspective as equipment - both new and refurbished – especially when (re)manufactured to the high quality requirements of the FDA and CE approval processes⁵⁵. A refurbished system offering the same functionality and quality of a new machine at the time when it was originally manufactured, with a similar warranty and support contract but at significantly lower price (20-60% compared to new equipment⁵⁶) could be optimal for any market context.

⁵⁴ European Commission, “The Blue Guide on the implementation of EU product rules 2016”, Published Jul 2016, Available at: <http://ec.europa.eu/DocsRoom/documents/18027/>

⁵⁵ Based on stakeholder interviews

⁵⁶ *Ibid.*

4. Analysis of the EU competitive positioning

The current section elaborates on the strengths and potential of the EU regions, key risks and challenges, as well as the opportunities for the EU regions. Stakeholders reported that while Europe has good market penetration and robust demand for refurbished systems, the variability in demand and supply for refurbished systems globally means that the business case is significantly hampered when not able to operate freely and internationally⁵⁷.

For Europe-based players like Siemens Healthineers and Philips, the advantage is in state-of-the-art research, development and feature innovation of new equipment. The market is highly competitive, and investing in entry models for emerging markets, even though this is a large and growing market, is not seen as a strong strategy⁵⁸. From this perspective, the refurbished medical equipment market is an attractive proposition for OEMs, as this gives their equipment a longer revenue-generating lifespan while creating a steady market for state-of-the-art equipment at multiple price points. In fact, most stakeholders reported that they do not see refurbished systems as “cannibalising” the market for new systems, and rather as an additional market at lower price points⁵⁹.

4.1 Strengths and potential of the EU regions

In this sub-section, we address the potential for developing large-scale manufacturing in Europe, expected Europe’s global position in 2030, key competitive advantages of Europe, as well as regions that could be in the lead.

Potential for developing large-scale manufacturing (refurbishing operations) in Europe

According to stakeholders, there is a high market potential for this domain in Europe. Most OEMs with major market share are either headquartered in Europe or have heavy presence in European markets due to the high margins on sale of new medical equipment, and high demand for medical equipment in general, due to high quality of healthcare across European countries. Europe also has a highly skilled workforce for the refurbishment process, which is mostly manual and technical⁶⁰.

Although the market for medical equipment in countries across Western Europe is relatively saturated, there is steady demand for equipment upgrades, be it new or refurbished. Since capital medical equipment requires regular recertification, many end-users (mainly imaging clinics, hospitals and pharmaceutical companies) find it convenient to replace their existing systems with new ones rather than merely recertifying and maintaining old ones. This high turnover rate is also favourable for incoming supply of used equipment into the refurbished medical equipment market.

⁵⁷ Based on stakeholder interviews

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

On the demand side, healthcare services are facing heavy cost pressures, which makes refurbished systems quite attractive to consider. Moreover, there is a growing demand from the Central and Eastern European countries, and from potential in emerging markets like China and India (even though some of these markets are currently not open for importing refurbished medical devices). On the other hand, many emerging markets also have protectionist policies that restrict foreign OEMs from entering.

Moreover, the well-defined regulatory landscape in Europe and the United States is also quite attractive for large scale manufacturing operations, with the exception of certain regulations which are reported to significantly hamper operations and artificially restrict market size⁶¹. Especially for the refurbished medical equipment market, the business case is essentially global, and so international business-friendly policies are likely to accelerate the growth of European operations.

Another promising area for growth is to capitalise on online marketing and sales, with intuitive catalogues, responsive customer interaction and digital customer support. Salesforce in this area still tends to be traditional, and could benefit greatly for digital ways of working.

Europe's global position in 2030

According to stakeholders, it is hard to predict Europe's position in this market that far ahead due to several reasons. Firstly, the impact of Brexit and similar geopolitical upsets introduce a lot of uncertainty about the future. Secondly, key competitors based in the United States and Japan are also constantly innovating in a tight race for market share. Thirdly, some companies in China are also ramping up their know-how and manufacturing capabilities, and may eventually get a share of the global and European market by 2030.

Notably, due to the heavy cost pressure in emerging markets, innovations in medical equipment for those regions will target lower price points. As new equipment at lower price points enters the market, is likely to be quite competitive with refurbished equipment from incumbent OEMs. From a European business perspective, this could be a concern⁶². On the other hand, low cost contract manufacturers from China could also form partnerships with Europe-based OEMs/subsidiaries, which may be beneficial in terms of parts and components sourcing.

Key competitive advantages of Europe

The key competitive advantages include the following:

- Well-defined regulatory and business environment;
- Already existing market with high margins and healthy public funding;
- Heavy presence of major OEMs, each with strategic regional partnerships to propel refurbished devices in the market. Heavy consolidation efforts in the

⁶¹ Based on stakeholder interviews

⁶² *Ibid.*

- MedTech domain in general, leading to economies of scale and strong market shares across international markets;
- Well-developed healthcare system with steady demand for high-tech medical equipment;
 - Steady supply of used medical equipment due to high market penetration;
 - Good infrastructure and supply chain for high-technology manufacturing;
 - Availability of high skilled workers for manual-intensive technical refurbishment process;
 - Cost pressures in healthcare system internationally which makes refurbished systems attractive. Growing privatisation of hospitals within Europe and internationally increases competition and cost pressures, likewise growing the market for refurbished systems.
 - Good reputation for Europe in terms of quality and service in the international market. OEMs known for quality offering reimbursed systems with significant warranty and support contracts definitely helps the business case.
 - Growing popularity for sustainable business practices in developed countries. Growing (albeit slowly) acceptance for refurbished medical equipment globally.
 - Good outlook and potential market for state-of-the-art innovation for new products, which in turn drives demand and supply for upgrades (including refurbished systems) in the long run.
 - From end-users' perspective, refurbished medical equipment also provides the benefit of familiarity, minimising time and effort to learn new interfaces while integrating organically into already-existing processes. Similarly, such familiarity also allows personnel to share tacit knowledge more easily, contributing to highly trained and effective workforce.
 - High awareness of circular economy and resource efficiency concerns.

Regions that could be in the lead

Stakeholders suggest that most OEMs are based in Western Europe and rely on regional sales and distribution to reach all other European countries. So the typical names such as Germany, France, United Kingdom (UK), Spain and Italy are already home to the biggest markets within Europe and will continue to be in the lead. Countries like the Netherlands, Denmark and Belgium also have several companies' headquartered there, with established sourcing and talent chains.

On the other hand, since it is a niche market, many parts and components can be sourced within the EU, but not all. Similarly, while there is promising demand and supply within Europe, the variability is too high to make a promising Europe-only business case. As such, the possibility of trading equipment and parts internationally would definitely improve the business case for European operations as well, according to most stakeholders.

As mentioned above, the impact of Brexit on this market introduces a lot of uncertainty especially because the NHS is a major user of medical imaging equipment in this region.

4.2 Key risks and challenges

The key risks and challenges include:

- Rapid pace of low-cost innovations for the requirements of emerging markets, but that could eventually be price-competitive with refurbished medical equipment.
- Despite the favourable overarching regulatory framework across the EU, the EU Member States still considerably differ in many aspects, and that presents a slight barrier to enter the market and establish sales/distribution channels.
- OEMs are currently unable to take advantage of growing demand in emerging markets due to protectionist economic policies.
- In some regions, there is a strong negative sentiment regarding “second-hand” equipment in general, which reduces demand and sales of used medical equipment. Refurbished medical equipment enjoys some benefits due to the strong brand and reputation of OEMs.
 - In some regions, this may manifest in the form of “discriminative” reimbursement policies where amounts returned are lesser if diagnostic equipment is older than a pre-defined number of years.
- Certain regulatory frameworks within the EU are reported to be disadvantageous to the refurbished medical equipment business model, clashing with a key principle for product-related legislation in the EU⁶³.
 - During discussions on the EU Directive on Waste Electrical and Electronic Equipment (WEEE), the medical device refurbishment business faced some barriers regarding the shipment of previously used medical devices (Annex VI, 2 (b)). Any actions taken in the context of the EU Circular Economy Package need to ensure that used medical devices for refurbishment & refurbished devices are not treated as waste.
 - Refurbished medical equipment providers are currently unable to compete in public tenders due to certain requirements that used equipment do not meet, even though the functional capabilities of new equipment and refurbished equipment could be identical.
 - As mentioned before, certain regulations affect sales of medical devices that were first placed in markets outside the EU from entering the EU. This means identical systems with similar service histories would be treated differently depending on whether the system was first sold within the EU or not. This is seen in directives like RoHS, but is a more general issue. According to stakeholders, any new regulation in the future (such as MDR, Machinery Directive, Radio Equipment Directive etc.) and new standards (such as IEC60601) are also expected to create restrictive conditions on devices that were originally placed on the market outside the EU from being resold within the EU, even after a comprehensive refurbishment process.

⁶³ The principle whereby medical devices that have been placed on the market only outside the EU are to be considered as “new” when entering the EU for the first time is common to all product-related legislations, as per the Blue Guide on the internal market (see footnote 53).

- Medical equipment manufactured by OEMs needs to meet high standards of safety and compliance depending on the CE mark requirements at the time of introduction. Some devices are sold within the EU and some are placed on the market outside the EU.
- When devices that spent their first lifetime within the EU return for refurbishment and then placed on the market (made available) again, they hardly face any barriers and can be easily sold.
- However, when used devices from outside the EU return to OEMs for refurbishing, their resale on the EU market is perceived strictly as a “first placement in the EU market”. As such these devices now have to fulfil the latest EU regulatory requirements before they can be resold within the EU. However, the criteria may have changed from the requirements at the time of original manufacturing (as with the introduction of RoHS).
- Even though all refurbished systems are typically serviced to conform to the same criteria during the time of original manufacturing, there is no guarantee that they will meet the latest criteria. As can be seen however, for devices that were first placed outside the EU, they may only be sold within the EU if they meet these latest criteria. Notably, these devices are otherwise identical to refurbished equipment cleared for resale, the only difference being where their first lifetime was spent.
 - From a regulator’s perspective, there are more nuanced reasons for such stringent requirements. For example, it is not guaranteed that devices made available in non-EU markets undergo regular post-market surveillance, as they would be required to within the EU. Moreover, product-related Directives also account for certain economic factors, and this may not be the case in other territories. These considerations are equally important as bottom-line concerns.
- Meeting the latest criteria is not always feasible without extensive product modification. Extensive product modification not only damages the profitability of the refurbishment business case, it also significantly delays the time at which the product can enter the market due to the need for recertification. Moreover such product modifications are not allowed based on the definition of refurbishment that OEMs comply with, since a refurbished device should have the same intended use as the original device.
- In effect, these complications create a shortage of supply and hinders a circular business paradigm from fully unfolding.

4.3 Opportunities for the EU regions

According to stakeholders, Europe is strongly situated to grow this market. As quality of life and healthcare systems become better across the European countries, the demand for new and refurbished medical equipment will remain strong. Many of the parts and components can be sourced within Europe, and major OEMs already have heavy European presence. OEMs are already proactively growing the business case for refurbished medical systems, in some cases, for over a decade or more, and in the future as the market grows, OEMs will likely continue to dominate even the refurbished equipment market. While it is projected that incumbent OEMs will continue to have a strong market share and benefit when the refurbished equipment grows, more patients in the European Union could have access to high quality healthcare at lower cost.

There are a few big opportunities to leverage in the near future.

Focus on high-tech innovation: As competition from Asia (notably China and Korea) grows, new players from these regions will probably target the low-budget market share. However, according to stakeholders, European companies in this domain should continue focusing on state-of-the-art innovations to maintain the technological edge in the market instead of invest in “me-too” innovations.

Focus on high quality compliance of refurbished equipment as a competitive advantage: As the demand for used medical equipment grows globally, Europe can boost its market share by ensuring that all equipment shipped from OEMs and other refurbishers within EU meets high quality standards, and communicating these requirements to the Member States and international trading partners in order to establish a solid reputation for quality equipment at low cost.

Educating Member States, stakeholders and trading partners on the benefits of the Circular Economy paradigm: As the global population grows year after year, and the demand for goods and services grows alongside, the Circular Economy paradigm is crucial to balance development and sustainable resource consumption. Moreover, the benefits of Circular Economy are not only ecological, but also economic and social.

5. Policy implications

The current section aims to present specific policy recommendations on what needs to be done in order to strengthen the EU competitive position regarding this product in the coming years, and specifically on how to enable European industry to remain strongly positioned at the higher end of the value chain. We elaborate on measures with both the immediate and longer-term focus.

5.1 Measures with immediate focus

The following measures with immediate focus have been identified:

- **Implement the EU Circular Economy package:** policy makers need to develop a good understanding of the need, urgency and possibilities of Circular Economy, which implies processes that may greatly differ from traditional business processes. As such, policies that target linear business processes should not disadvantageously affect companies attempting circular economy business models.
 - Specifically with respect to refurbished medical equipment market, it is important to realise that shipments of pre-owned medical equipment entering the EU from outside for the purposes of refurbishment and possible resale should not be classified or treated as a waste management activity. Policies that are aimed at minimising transboundary movement of e-waste should not apply to legitimate shipments of medical equipment across regions within and outside Europe.
 - Similarly, restrictions on sales of refurbished medical equipment that were sourced from outside the EU disproportionately constrict the flow of identical medical equipment depending on whether they were first sold within or outside Europe. Such policies are not conducive to growing the circular economy paradigm where demand within Europe cannot be met with available supply outside Europe. Furthermore, this reduces EU healthcare providers and patients access to affordable and high quality refurbished devices.
 - Moreover, the circular economy paradigm should be recognised as a legitimate economic process, with high relevance and potential in the coming decades. Any funding, subsidies or incentives (e.g. reduced VAT) targeted at growing circular economy business models would be greatly beneficial for both business, society and economy.
 - The identified challenges need to be treated at the EU level, with monetary incentives and a comprehensive legal framework for product life extensions and material reuse.
 - Explore more opportunities to drive circular business models like refurbishing but also leasing, sharing and using instead of buying, by promoting equipment-as-a-service as a prevalent model of consumption.
- **Use the CE mark and Declaration of Conformity (DoC) as lifetime passport for refurbished medical equipment:** This is in general a solution to the

overarching challenge with Directives restricting sales of refurbished devices mentioned previously.

- It is recommended to structure CE labels and DoCs such that refurbished equipment that meets the standards of the original should be allowed to be sold in the market.
- Specifically, stakeholders' request is for the equipment to be required only to be refurbished to the same standards as the standards of the year of its release, as the standards are constantly evolving. If the equipment has to be refurbished in line with the latest standards (not the ones of the release year), the required changes in functionality and components are likely to be considerably higher to qualify for recertification as “fully refurbished” – which increases time and cost, jeopardising the circular business case for the OEM.
- **Allow refurbished medical equipment as viable candidate for public tenders and reimbursement policies:** in majority of public tenders, funding is sometimes reserved only for new equipment. However, as the cost pressure increases, allowing for refurbished systems with identical functionality would be beneficial for both businesses and healthcare providers. This move would remove one of the biggest barriers to enter the Central and Eastern European markets. At the same time, there is a need to engage and educate stakeholders to remove unjustified negative perceptions of refurbished medical equipment.
- **Funding to mitigate risks in business case for refurbishment:** in some ways, the business case for refurbishment can be more risky than manufacturing of new equipment, even though the process does not require R&D, and typically begins with a functional finished product.
 - The infrastructure for reverse logistics (wherein the channels that distribute products from a linear business cycle from manufacturer to end-user function harmoniously in reverse to support re-acquisition of product from user and transport back to service provider or manufacturer) does not exist in quite a form or strength to power a broader circular economy.
 - Moreover, manufacturers currently have more certainty about the supply of parts and demand for new products than the supply of used equipment and the demand for refurbished products. This leads to higher inventory levels in order to buffer fluctuations of supply and demand, resulting in tied-up capital.
 - The EU funding to support the growth of the infrastructure required for circular economy initiatives would not only help the market for refurbished medical equipment, but would also broadly grow the business case for circular business models across multiple sectors.
- **Increase clarity of regulatory frameworks for compliance⁶⁴:** some stakeholders mentioned that European Directives for medical equipment, and especially special considerations for refurbished medical equipment, are not as clear or well-defined as the US FDA guidelines. Increasing the level of clarity

⁶⁴ BSI group, “Top Ten CE marking issues”, Published 2015, Available at: <https://www.bsigroup.com/meddev/LocalFiles/en-GB/Events/UK-Consultants-Day-2015/BSI-md-consultants-day-top-10-CE-marking-issues-presentation-UK-EN.pdf>

could vastly decrease uncertainty and corresponding inefficiency from manufacturers' processes. There is a need to engage trade associations like COCIR and DITTA in a dialogue to address concerns and challenges jointly.

- **The potential for private-public partnerships can be greatly increased by finding and growing Digital Single Market synergies⁶⁵:** As mentioned earlier in the report, there is a growing trend of uberisation across industries, leveraging digital technologies to redistribute under-utilised resources while improving access. Industry groups like COCIR⁶⁶ are already bringing together multiple companies across multiple industries – from OEMs to telecom operators and healthcare IT. It is a natural area for finding and growing regional synergies by leveraging digital technologies as the “glue” between both private and public sector players in this space.

5.2 Measures with longer-term focus

The following measures with longer-term focus have been identified:

- **Increase compatibility between CE certification and FDA approval:** (this is part of a broader political discussion, that applies to more than just refurbished medical equipment, but for medical technologies in general; still, it is an area of focus that could impact the target industry as well). Currently, it is not the case that a device that has already received FDA approval can experience a faster CE mark certification process or vice versa. In the EU, multiple Notified Bodies⁶⁷ are responsible for regulatory approval and monitoring. This makes the CE mark certification process rather complex, even for products that have already passed equally stringent FDA approvals.
 - By more closely aligning the approval criteria and testing processes between the US and the EU, new products could be standardised and tested across territories even quicker.
- **Open bilateral discussions with emerging markets against protectionist policies:** for high technology products and especially circular economy products, the refurbished equipment market can naturally help feed the growing demand from emerging markets.
 - The advantages are not just monetary but also resource-based. China, India, Brazil and fast-growing markets in Africa are developing rapidly, with hundreds of millions potentially entering the middle class. In a linear market model, servicing the needs of this growing group of consumers with only new equipment would mean disproportionate amounts of resource consumption, especially when perfectly functional equipment is already available.

⁶⁵ European Commission, Digital Single Market – Private Public Partnerships, Accessed Oct 2017. Available at: <https://ec.europa.eu/digital-single-market/en/public-private-partnerships>

⁶⁶ COCIR, “About COCIR”, Accessed Sep 2017, Available at: <http://www.cocir.org/about-cocir.html>

⁶⁷The NANDO database lists all Notified Bodies for the different Directives: <http://ec.europa.eu/growth/tools-databases/nando/index.cfm> ('Notified bodies' are accredited by the Member States of the European Union and then notified to the European Commission and to the other member states).

- Moreover for high technology products, European and American products with local partnerships and supply chains can aid in technology transfer to host regions while increasing access to a growing group of consumers.
- As such, bilateral and regional dialogues should be used to promote a wider understanding of refurbished products.

Annex A: List of interviewees

Table A-1: Overview of the interviewed stakeholders

| Nr | Name | Position | Organisation | Country | Stakeholder type |
|----|--|---|--------------------------------|-----------------|-----------------------|
| 1 | Yutaro Takahashi | Mechanical Design Engineer | MILabs | The Netherlands | OEM |
| 2 | Jeroen van Nistelrooij | Marketing Director for Refurbished Systems | Philips Healthcare | The Netherlands | OEM |
| 3 | Patricia Gehlein and Christian Schlecker | Government Affairs & Policy for Refurbished Systems | Siemens Healthineers | Germany | OEM |
| 4 | Johan Vochteloo (pending) | Manager Refurbished Systems Secondlife | Toshiba Medical Systems Europe | The Netherlands | OEM |
| 5 | Dr. Falko Riechert | Principal | Strategy& | Germany | Subject-matter expert |

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