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The impact of the Critical Raw Materials Act on the prospect of EU healthcare industry

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Abstract

The EU Critical Raw Materials Act is the first regulatory policy on critical raw materials with concrete objectives and measures that contribute to building and strengthening of a resilient industrial value chain in the EU. This master's thesis identifies the overlapping interests between the EU government and EU technology-driven industries as well as their innovative reactions in accordance with Strategic Autonomy. Based on the principle of open strategic autonomy, the EU Critical Raw Materials Act aims to deal with challenges posed by increasing external uncertainty. The regulation includes three pillars: capacity building in the EU, diversification of global partnerships, innovations in recycling and substitutes. Using the EU healthcare industry as an example, the master's thesis analyses the supply chain and value chain of magnetic resonance imaging systems, YAG:lasers and the EU Strategic Project cochlear implants devices to illustrate the adaptation of companies to mitigate supply risks of critical raw materials. The master's thesis demonstrates the steering role of policy in business practices by analysing the active business pathways to reduce dependencies on critical raw materials from the perspectives of EU multinationals and local companies.

Abstrakt

Das europäische Gesetz zu kritischen Rohstoffen ist die erste regulative, politische Maßnahme mit konkreten Zielen zum Aufbau und zur Stärkung einer widerstandsfähigen industriellen Wertschöpfungskette bezüglich den kritischen Rohstoffen innerhalb der EU. Diese Masterarbeit identifiziert die überschneidenden Interessen sowie deren innovative Reaktionen zwischen der EU-Regierung und den technologiegetriebenen EU-Industrien. Basierend auf dem Prinzip der offenen strategischen Autonomie, zielt das europäische Gesetz darauf ab, die von zunehmenden, externen Unsicherheit verursachten Herausforderungen zu lösen. Die Verordnung besteht aus drei Säulen: Aufbau europäischer Kapazitäten, Diversifizierung globaler Partnerschaften sowie Innovationen bei Recycling und Ersatzstoffen. In der Masterarbeit werden am Beispiel der EU-Gesundheitsindustrie die Liefer- und Wertschöpfungskette von Magnetresonanztomographen (MRT), YAG:Lasern und dem EU-Strategieprojekt Cochlea-Implantate (CI) untersucht, um Anpassungsmaßnahmen von Unternehmen zur Reduktion von Versorgungsrisiken bei kritischen Rohstoffen zu veranschaulichen. Die Masterarbeit zeigt die lenkende Rolle der Politik in der Unternehmenspraxis auf, indem die Verringerung der Abhängigkeiten von kritischen Rohstoffen aus der Sicht von multinationalen EU-Unternehmen und lokalen Unternehmen analysiert wird.

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Abbreviation

ATO	assembly-to-order
CI	cochlear implants
CRMs Act	Critical Raw Materials Act
CRMs	critical raw materials
EoL-RIR	end-of-life recycling input rates
ETO	engineer-to-order
FTA	free trade agreement
HREEs	heavy rare earth elements
LREEs	light rare earth elements
MNC	multinational company
MRI	magnetic resonance imaging
MTO	make to order
OEM	original equipment manufacturer
OSA	open strategic autonomy
SCM	supply chain management
SRMs	strategic raw materials
VCM	value chain management
YAG	yttrium-aluminium-garnet

1. Introduction

1.1. Background

In March 2023, the European Commission released the proposal for the European Critical Raw Materials Act (CRMs Act). Then, after the adoption of the proposal by the European Parliament in December 2023, the European Council gave its final approval on the Critical Raw Materials Act in March 2024. The result is recognised as a great step for critical raw materials policy. As the first regulatory framework for the EU's common interests on critical raw materials issues, the CRMs Act is expected to push forward policy implementation in a more effective way (Hool, et al., 2023).

The Critical Raw Materials Act views critical raw materials (CRMs) as 'indispensable inputs for a wide set of strategic sectors including renewable energy, the digital industry, the space and defence sectors and the health sector' (European Commission, 2023c). A diversified, affordable and sustainable supply of CRMs is an important guarantee for the EU's strategic and high-tech industries and the EU's resilience in the long run (European Commission, 2024). The EU has a high reliance on imports of critical raw materials from third countries (European Commission, 2023c). High reliance can lead to high risks of being harmed by supply disruption (Blengini, G.A. et al., 2020). As critical raw materials are essential from the beginning of the industrial value chain, frequent lack of necessary resources is highly likely to impede the manufacturing process and bring negative effects to the economy (European Commission, 2023c).

Furthermore, the EU's supply chain management of critical raw material is related to the EU's conception of open strategic autonomy (OSA). Open strategic autonomy is a conceptual cornerstone of the European Commission's new trade strategy and is rewriting the rules of openness in the EU trade sector (European Commission, 2023d). The CRMs Act is a product based on the principle of open strategic autonomy. The European Council considers that reducing dependencies on critical raw materials can create more opportunities for the EU's resilience and independent development (European Council, 2024a).

The CRMs Act has identified thirty-four critical raw materials with high economic importance and high supply risks (European Commission, 2023c). A series of goals regarding mining, processing and recycling have also been clarified by the Act (European Commission, 2023c). To achieve the goals, a variety of measures are applied to support the implementation of the policy. To be concrete, the CRMs Act aims to better leverage strengths and capacity of the Single Market, to extend the EU's external partnerships and to promote investment in the EU's mining and processing projects (European Commission, 2023b). CRMs policy has a continuous and long-lasting impact on all relevant industries. It is important for industries to leverage the opportunities and challenges brought by the implementation of CRMs policy to achieve their goals of strategic development.

The healthcare industry is a pillar industry in Europe thanks to the EU's well-developed welfare system and consumers' increasing awareness of their health condition and pursuit for beauty. According to the European Investment Bank, the healthcare industry accounts for 8% of the total workforce and for 10% of its GDP of the EU's economy. From 2000 to 2020, the devotion of GDP to healthcare has grown from 7,5% to 10,9% (eurostat, 2023a). In addition, the export of medical devices and pharmaceutical products can also generate enormous income for the EU.

Medical devices are indispensable for good medical performance. Sufficient supply of medical devices requires adequate supply of critical raw materials. Supply shortage of CRMs may result in value chain erosion which will be further delivered to manufacturers, customers and consumers (Deloitte, 2022). It is important to understand how the EU healthcare industry is influenced by CRMs policy and how it adapts itself to policy. To master the relationship between policy influence and business decision is important for further adjustment and implementation by policy makers and is equally important for business managers to perform better in the given context.

In view of the above facts, this master's thesis will study the impact of the Critical Raw Materials Act on the value chain and supply chain of EU healthcare industry, to be specific, the impact of diversification of global sourcing, applicable innovation on recycling and substitutes as well as domestic capacity building in mining and processing on the value chain and supply chain of EU healthcare products manufacturing.

1.2. Research questions and hypothesis

1.2.1. Research questions

As a main concern of the policy making of the CRMs Act is its contingency with OSA. It means that, to a great extent, industries and companies with common interests with OSA will be more involved, when it comes to the issues like autonomy, multi-channel sourcing, technology innovation and entrepreneurship in the value creation.

In view of these concerns, this master's thesis will answer the following questions:

(1) How will the EU Critical Raw Materials Act influence the EU healthcare industry?

(1a) What kind of impact will the policy on 1)geographical diversification of global suppliers, 2)mining and processing capacity building and 3)recycling and substitute materials have on the supply chain of medical devices manufacturing?

(1b) What kind of impact will the policy on 1)geographical diversification of global suppliers, 2)mining and processing capacity building and 3)recycling and substitute materials have on the value chain of medical devices manufacturing?

(2) How can the EU healthcare industry adapt itself to the EU Critical Raw Materials Act?

(2a) What kind of capabilities do the EU healthcare industry have to build or enhance in order to adapt itself to the EU Critical Raw Materials Act?

(2b) To what extent can these capabilities help to reduce the EU healthcare industry's supply dependencies on critical raw materials?

1.2.2. Hypothesis

(H1) If the policy on 1)geographical diversification of global suppliers, 2)mining and processing capacity building and 3)recycling and substitute materials can be implemented adequately,

(H1.1) it can reduce the strong dependencies of CRMs from the third countries in the healthcare industry, specifically, in medical devices manufacturing.

(H1.2) the operation of the supply chain of the healthcare industry, specifically, of medical devices manufacturing can be enhanced.

(H1.3) the architect of the value chain of the healthcare industry, specifically, of medical devices manufacturing can be enhanced.

(H2) The EU healthcare industry’s resistance to supply risks of critical raw materials depends on its capabilities building and adaptation to the EU Critical Raw Materials Act.

1.3. Goal and structure

The aim of this thesis is to understand the relationship between policy decisions and industrial activities, for instance, the role of policy in the development of companies and changes of strategies. The Critical Raw Materials Act highlights the importance of CRMs and is highly related to the high-tech industries. The healthcare industry is a high-tech industry: the quality and quantity of CRMs plays a vital role to transform scientific performance to medical service performance. The research will provide a good example for understanding the function of CRMs Acts on other strategic high-tech industries from an evolutionary perspective.

- To understand the function of a strategic EU-level policy on the EU firms' strategic decision making.
- To understand the construct of supply chain and value chain in a high-tech industry with a solid base of manufacturing and technological innovation.
- To understand the opportunities and challenges for independent industrial development in an increasingly dynamic global context.
- To provide an active thinking for EU firms on self-adaptation to policy, independent self-development, their international and EU-wide cooperation.

The first chapter describes the background of the topic and poses research questions and hypotheses.

The second chapter contains the literature review for (open) strategic autonomy and CRMs policy, followed by supply chain and value chain management theories. There is an analysis on the relationship of the supply chain and the value chain of CRMs and medical devices manufacturing in the EU.

The third chapter explains the methodology of this study and the reason for the choice. The research methods used in the thesis are multicase study and cross-case study. The theoretical framework is based on Rehman and Ali's five strategies for the healthcare supply chain resilience from a risk control perspective and Holweg and Helo's Five-points model regarding the value chain architecture.

In the fourth chapter, three representative cases are analysed. They are magnetic resonance imaging devices (or MRI systems) for diagnostics science, YAG:lasers for surgeries, cochlear implants devices for prosthetic implants. Apart from the analysis on the supply chain and value chain of CRMs in these three cases, there is a comparative analysis on multi international firms with a European origin and local firms. Based on the findings, a further discussion on the CRMs Act and the EU medical devices manufacturers will be held.

The fifth chapter will conclude the findings of the study, summarise answers to the questions and give suggestions to further research.

2. Literature Review and Conceptual Framework

2.1. Global context

From an economic perspective, market competition and cost efficiency drove companies to seek materials in resource-rich and low-cost countries. In the last two decades, great economic and social changes in the European countries accelerated the expansion of companies globally, from production to sales. Demographic growth, rapid development of the global middle class, growing urbanisation and green transition kept expanding the market prospect globally (Christmann, 2021). Then, the market experienced a strike back during the Covid-19 pandemics due to worldwide continuous interruptions in the supply chain and soaring prices of raw materials, manufacturing and products (European Parliament Research Service, 2022b). In addition, increased unemployment and reduced buying power also demotivated production (Christmann, 2021). The realisation of the EU resilience pushed policy makers and industrial managers to remodel traditional supply chain and value chain, with the goal of transforming challenges into opportunities.

Globalisation is the main stream for the world economy. Market-based global value chain is essential for international co-creation of value. In the last two decades, multinational companies (MNCs) extended the value chain in host countries with relatively richer resources and lower costs than home countries. MNCs' business activities not only increased participation of developing countries in the global market but also generated more choices for new suppliers for MNCs (Miró, 2023; Benito et al., Ernst & Kim in Zahoor et al., 2023). At the same time, earlier knowledge transfer stimulated more and more countries to take part in technological competition, thus, intensified competition among countries for critical raw materials (Hool, et al., 2023). Moreover, economic upgrading of countries made it possible for a shift towards a higher position in the global value chain and challenge the already formulated labour division across the global supply chain (Gereffi et al., 2021). That means, resource-rich countries began to support their own strategic industries and also joined the competition for critical raw materials. Increasing rivalry among global suppliers and protection of technological achievement have led to the slowing down of globalisation in strategic areas and elevated emphasis on technological sovereignty (Evenett, 2019).

At the expansion stage of globalisation, business-oriented internal factors such as cost efficiency play a relatively important role in strategic decision making. Nowadays, the weight of external factors, particularly geopolitical and geoeconomic factors, has increased significantly for those CRMs-based, technology-oriented industries. While some researchers hold a pessimistic point of view and point out the trend towards protectionism concerning contextual protectionism policy instruments including but not limited to embargo of export, tariffs, quotas and increasing subsidies for local industries (Zahoors et al., 2023), other researchers regard the slowing down of globalisation a strategic chance for reorganisation of the global supply chain and value chain (Miró, 2023; Marx, 2023; Hool, *et al.*, 2023).

Scholarly debate also runs about the trade-off relationship between a country or a region's global industrial interdependence and establishment of the region's own supply chain capabilities (Contractor, 2021; Witt, 2019). A striking example is the threat of 'a strong tendency to return to unilateralism' in nowadays international relationships. The threat is damaging multilateral interests and multilateral conduct set by international institutions (Beaucillon and Poli, 2023). The recent examples of this retreat can be the UK's Brexit, the upgraded trade war between the US and China, Russia's invasion of Ukraine and so on (Beaucillon and Poli, 2023; European Parliament Research Service, 2022b).

From 2017 to 2019, there was an increasing stress for the EU in global trade, e.g. the EU's weakened relations with the UK by Brexit, the US' 'American First' protectionism and economic expansion of China (European Parliament Research Service, 2022a; Lavery and Schmid, 2021). The notion of 'nationalism, identitarianism, protectionism and isolationist sovereignism' (Emmanuel Macron, 2017 in European Parliament Research Service, 2022a) expressed worries about the EU's resilience threatened by increasing global tension, euro's weakness against US dollars and other external risks (European Parliament Research Service, 2022a). The problem of the EU' insufficient autonomous operating capabilities emerged and the urgency of capability building became the highlight in many policy areas (European Parliament Research Service, 2022a).

In 2020 and 2021, the Covid-19 exposed the problem of the EU's supply chain vulnerability referring to medical and pharmaceutical products, raw materials, not to mention, semiconductors which are also indispensable components for technological products including medical devices (European Parliament Research Service, 2022a). The problems resulting from a high concentration of sourcing usually can be much more sensible during a crisis (European Parliament Research Service, 2022a).

The Ukraine War in 2022 not only intensified 'global geopolitical competition', but also fueled the speculation and price volatility in the world energy and raw materials market (European Parliament Research Service, 2022a). Instability and uncertainty of the global context has an impact on changes in a variety of policy areas. Changing policies require solidarity among EU Member States and consensus on issues like reducing dependencies on supplies from third countries.

Furthermore, the 'new global disorder' (Lavery and Schmid, 2021) challenges the EU's consensus on neoliberalism and further resilience (Schmitz and Seidl, 2023). It is of crucial importance for Europe to rethink and reorient its roles and interests in the world and to enhance the efficiency of decision making in economic, industrial and trade policies (Schmitz and Seidl, 2023; Molthof and Köbben, 2022).

2.2. The history of the EU’s Critical Raw Materials Policy

Policy decision making concerning CRMs issues is supported by a series of researches and policy practices. The screening and evaluation of raw materials' criticality in the EU began in the early 2000s (Hool, *et al.*, 2023). Technological innovation, increasing manufacturing capacity and industrial structural transformation stimulated the demand for certain types of raw materials. In 2005, the first CRMs study was conducted by an EU-level research team, followed by the Raw Materials Initiative (RMI) in 2008 and the first list of CRMs in 2011 (Hool, *et al.* 2023). As the consequences resulting from supply disruptions could to be very challenging, it is important to 'guarantee undisturbedness of access to CRMs' resources' (European Commission, 2008; Gstöhl and Schnock, 2024). The RMI established the three pillars:'1)ensuring a level playing field in access to resources in third countries; 2)fostering sustainable supply of raw materials from European sources; 3)boosting resource efficiency and promoting recycling' (European Commission, 2008). Emphasis was laid on international cooperation which referred mostly to diplomatic efforts, e.g. FTAs with a list of third countries like Mexico, Chile and New Zealand (Gstöhl and Schnock, 2024). The first CRMs policy document has some limitations. The description of resource-rich countries and like-minded countries was vague and there wasn't a clear priority of diplomatic tasks concerning CRMs resources. The role of industrial participants is limited, when industrial stakeholders only took the tasks on research on recycling and substitutes.

Then, there came the foundation of the European Innovation Partnership for Raw Materials (EIP-RM) in 2012 and the Strategic implementation plan (SIP) by EIP-RM in 2013. The EIP-RM created a stakeholder platform which aims to reinforce RMI from policy framework to actions and expressed the idea of mobilising stakeholders including governments, industry, academia and non-governmental organisations. The SIP listed the two parallel objectives concerning CRMs sourcing issues and the control of the externality of the plan. Issues about CRMs' exploration, mining, processing and recycling were all mentioned as pilot actions in SIP. However, mining and processing could cause environmental externality and thus was not accepted by those Member States with reserves of CRMs.

In 2017, the European Commission published new methodology and more accurate criteria for CRM's criticality assessment. The method focused on CRMs' applications in manufacturing, trade, substitutes and recycling as well as domestic sourcing possibilities. Concrete reasons for supply risks have been added into consideration, e.g. 'specific allocation of raw materials to the relevant end-use applications and corresponding manufacturing sectors' (European Commission, 2017a). 'Specific allocation' needs support from policy on CRM's circularity issue. According to the 'Report on critical raw materials and the circular economy', the problem of inadequate enforcement of circular economy policy should be dealt with. The report encouraged recycling of complex end-of-life products such as waste of electrical and electronic equipment. The 'Recovery of critical and other raw materials from mining waste and landfills' provided a few examples with practical and theoretical insights. Furthermore, 'specific allocation' needs an extension of the EU's role in the supply chain, especially when the amount of CRM's demand is known and specific. According to the 'Report on raw materials for strategic technologies and sectors' (2020), 'the EU plays a major role only at the assembly stage'.

In 2020, the European Commission published 'Critical Raw Materials Resilience: Charting a Path towards Greater Security and Sustainability', in which ten actions were identified with a list of actors for each action. The actions referred to the launch of an industry-driven European Raw Materials Alliance, sustainable financing criteria for the mining, extractive and processing sectors, research innovation and skills cultivation on waste processing, recycling and substitution and so on (European Commission, 2020a). As the world's largest innovation community in the raw materials sector, the task of the Alliance is to focus on the strategic and collective value creation along the industrial value chain (European Commission, 2020a).

The 2020 criticality assessment of CRMs used improved criteria based on its 2017 version. In the 2020 version, the importance of end-use applications and the value added for manufacturing sectors have been introduced to the economic importance criteria. And the supply risks criteria has introduced global concentration of the materials, EU's import reliance for the materials and the potential for recycling and substitution for the materials. The assessment of the fourth list of CRMs also showed an increasing focus on the importance of extraction and processing in the value chain (European Commission, 2020c).

In March 2023, the European Commission published the 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020'. The Proposal was accepted by the European Parliament in December 2023 and legislated by the European Council in March 2024. The legislation of the Critical Raw Materials Act is a milestone for critical raw materials policy and a contribution to the EU's strategic autonomy with more clarified aims and more diversified policy instruments. In addition, the CRMs Act is considered as part of its broader 'Green Industrial Plan' and in conjunction with a 'Net-Zero Industry Act' (Hool, *et al.,* 2023). The CRMs Act shows an increasing cohesion with other EU policies, when it shares the same goals with other EU policies.

From 2008 to 2024, CRMs policy has experienced slow but large progress. 'The Critical Raw Materials Act's provisions are transformative by utilising industrial policy instruments and can be seen as a result of two decades of EU efforts and policy dialogue to actively mitigate supply risks' (Hool, *et al.,* 2023). Behind the evolutionary changes of CRMs policy issues, there are not only great changes in the EU's economic and societal situation, but also increasing uncertainty in the global market in a dynamic geopolitical and geoeconomic context. Current CRMs policy is the answer to the existing and emerging challenges.

Publications	Strategy	Content
Raw Materials Initiative (2008)	International: ensure access to raw materials from international markets. Domestic: set the right framework conditions. Recycling: promote recycling to reduce the EU's consumption of primary raw materials.	Launch of EU strategic raw materials diplomacy. Promote research on extraction and processing. Promote recycling of secondary raw materials.
Strategic implementation plan by European Innovation Partnership (2013)	Technology: technologies for primary and secondary raw materials' production. Non-technology: improve the EU framework conditions of raw materials. International: improve cooperation with like-minded countries and resource-rich countries.	Promote innovation on exploration, refining, processing, substitution, recycling. Improve minerals policy framework and optimise flows of materials and waste. Improve global raw materials governance and dialogue, technological cooperation, knowledge transfer and investment.
Report on CRMs and the circular economy (2018)	Sectorial: cooperation across the supply chain; promote circular economy action plan in all involved industries.	Build raw materials scoreboard amd circular economy monitoring framework. Cooperate with advanced mining countries outside the EU.
Recovery of critical and other raw materials from mining waste and landfills (2019)	Technological: manage extractive waste and enhance landfill mining.	Recovery of CRMs and valuable metals from old mine or industrial waste streams, bauxite residue.
Critical Raw Materials Resilience: Charting a Path towards greater Security and Sustainability (2020)	Value chain: develop industrial value chain resilience. Circularity: circular use of resources, sustainable products and innovation. Domestic: strengthen domestic sourcing and processing. International: diversify sourcing from third countries based on rule-based open trade.	Launch an industry-driven European Raw Materials Alliance and develop sustainable financing criteria. Focus on secondary materials. Identify mining and processing projects and strengthen expertise. Develop strategic and pilot partnerships and promote responsible mining practices.
Critical raw materials for strategic technologies and sectors in the EU - a foresight study (2020)	Industrial and technological.	Assessment of 15 technologies in 5 strategic sectors. Forecasting the demand for CRMs for technologies in 2030 and 2050.
EU circular economy action plan (2023)	Value chain: create a well-functioning internal market for high-quality secondary raw materials.	Develop EU-wide end-of-waste and by-products monitoring and standardised management for certain waste streams.

The Critical Raw Materials Act (2023)	Domestic value chain: strengthen the Union raw materials value chain.	Implementation of Strategic Projects and improve permit granting process, coordinate financing, etc.
	Risk management: Risk monitoring and mitigation.	Strategic partnerships, strategic stocks and monitoring, joint purchasing.
	Circularity and environmental sustainability.	Explore CRM recovery potentials, promote extractive waste recovery and circularity of permanent magnets.

Table 1: The development of the EU's critical raw materials policy

2.3. A review of existing literature

2.3.1. Open strategic autonomy

The term 'strategic autonomy' originated from the EU Common European Security and Defence Policy (CSDP) and the EU Common Foreign and Security Policy (CFSP) since 2013. The term emerged in the 2016 EU Global Strategy which was a sign of the EU's ambition confronting global challenges. The expansion of embeddedness of 'strategic autonomy' in a variety of policy sectors began in 2017 (Tocci, 2021). In 2019, the European Commission provided a more comprehensive interpretation of 'strategic autonomy' with an addition of 'openness' in industrial and digital sectors, whereby 'openness' involving the concept 'value creation' should be an essential support to enhance the EU' capabilities to realise 'strategic autonomy' (Tocci, 2021). The enriched comprehensiveness of strategic autonomy from defence and security to other policy sectors demonstrates the EU's interests and values towards global challenges (Botti, *et al.*, 2021). Since 'economic interdependence is becoming more politically conflictual than in the past', OSA principle has become an angle for policy making to realise the EU's resilience in a dynamic geopolitical and geoeconomic global context (Beaucillon and Poli, 2023).

From being one of the most open economies in the world to the conditional and qualified openness in OSA, this change is not only the EU's response to global disorder, but also a call for internal unity (Rodrik, 2011 in Miró, 2023; Schmitz and Seidl, 2023). Open strategic autonomy aims to build the EU's capacity to overcome the constraints brought by institutional complexities and international conflicts (Raza, 2021). In economic and trade areas, OSA insists not only on the enhancement of the EU's industrial capabilities to better serve the EU industrial transition and transformation, but also on the EU's leadership and assertiveness in critical fields, technologies and global market competition (Dominick, *et al.,* 2023; Raza, 2021).

Adding 'open' to 'strategic autonomy' equips the political principle with more policy coherence and coordination in the economic sector. It eases the tension brought by strategic autonomy and expresses an understanding of the compatibility of trade openness and strategic autonomy. While strategic autonomy firmly insists on the EU's interest in defensive and economic security, open strategic autonomy inclines to find a balance between independence and international cooperation (Hool, *et al.,* 2023). 'Achieving strategic autonomy while preserving an open economy' is a key objective for the EU as well as a long-established approach to globalisation (European Council, 2020). In addition, it should be mentioned that the scope of application of 'open' and 'strategic autonomy' is not overlapped. The application of 'open' can be multilateral wherever possible and appropriate, while 'strategic autonomy' puts critical emphasis on strategically important policy areas (Dominick, *et al.,* 2023).

OSA is principally important for EU economic resilience and supply security. First, OSA supports the enhancement of the EU's industrial capabilities through dealing with inefficiency caused by supply disruption (European Commission, 2023d). The enhancement of industrial capacity needs the support of trade openness. To maintain trade openness, it is necessary to balance the trade system, which means, to diversify international cooperation as well as to make good use of the integrity of the Single Market (European Commission, 2023d).

The fact that the EU has a necessity to balance the trade system implies that interdependencies on materials and products between the EU and third-countries can not be easily broken up. From the perspective of OSA, it's reasonable to reshape interdependencies by applying 'partner selection criteria'. This measure is thought to be proactive to manage economic and technological interdependencies, to promote shared values and to create long-term sustainability altogether (European Commission, 2023d).

The integrity of the Single Market has a synergy effect on the implementation of OSA-related policies. There is an argument that 'reshoring production to Europe' can support the EU resilience through building the EU's capabilities (Domnick *et al.*, 2023). Application of reshoring of production should be 'focused on specific critical sectors and products with pronounced supply bottlenecks' (Raza, 2021), for example, in the EU's sensitive key areas which constitute the EU' industrial ecosystem, including critical raw materials, health, defence, energy, digital and space (European Council, 2020d). Moreover, openness within the

Single Market can encourage financial flows in the EU and encourage multinationals to create opportunities for collaboration and innovative business in Member States with potentiality for pertinent industrial collaboration projects (European Commission, 2023d). What's more, there is an expectation for more transparent, timely and unified EU-wide tracing systems for supply chains in critical industries, for example, the data of suppliers of critical pharmaceutical substances and monitoring of supply security (European Commission, 2023d.

Second, OSA supports the EU's resilience through industrial digital and green transition after the Covid-19 (European Commission, 2023d). The key idea of embeddedness of OSA in industrial policy is to manage supply chain dependencies and to develop value chain's sustainability (Botti, et al., 2021; Molthof and Köbben, 2022). Open strategic autonomy serves to steer the direction of the EU economic transition for the EU' interests, which should be independent from the potential hurdles in the global supply chain for the EU industry (European Council, 2020d). Efficient utilisation of raw materials and recycled materials, e.g. recycling from end-use products and secondary materials, is important to reduce supply risks and to scalp value of resources in value chains. However, it should not be forgotten that possible inefficiency exists in value chains due to costly new investment. If European industries wish to adapt themselves to a new construct of value creation, the sustainability of this new model can be guaranteed in the long run and make sure the investment gets returns later (Botti, et al., 2021). Furthermore, to realise autonomy through industrial transformation and gain sustainable competitiveness, well-organised investment and funding is also crucial in comparison to investor countries, for example USA and China, whose venture capital mode is widely applied to Netsero and healthcare industry (European Commission, 2023d).

Third, OSA can strengthen institutional ability to coordinate and collaborate between EU policy areas, public and private actors in the complex system of multi-level governance (Dominick, *et al.*, 2023, Raza, 2021). However, the prerequisite for greater achievement is the EU's capabilities in collective actions among Member States (Miró, 2023). The EU's internal coherence can contribute to the re-strengthening of the EU's external power (Sutton 2007, in Miró, 2023). As long as the EU and Member States accept OSA as an important conceptual thread for the resilience of industry, supply and the market, OSA can serve the reinforcement of European cooperation and integration to create favourable sustainable market environment and realise added value of strategic autonomy (European Council, 2020d; Beaucillon and Poli, 2023)

Botti, *et al.*(2021) argues that OSA neither rejects efforts and efficiency of globalisation, nor resist further development of global multilateral collaborative relationships. But, to maintain a rule-based international order in a global context with fiercer competition and more uncertainty than in the last decades, there is a necessity for the EU to increase its resilience capacity to gain more 'assertiveness against unfair practices undermining the effectiveness of multilateral institutions' (Botti, et al., 2021). Molthof and Köbben (2022) argues that OSA in trade and industry sectors reduces strategic dependencies while protecting the EU industry from external economic coercion and unfair trade. The authors perceived that the nature of strategic autonomy has an inclination of protectionism and suggested to increase the weight of 'openness' through maintaining fair competition within the Single Market, strengthen global partnerships based on reciprocal agreements as well as fostering a rule-based multilateral trading system. The former emphasises the EU's positioning and function in the world and reconstruction of rules; the latter views OSA as a strategic response to the interests' difference between the EU and the world.

Rieker and Giske (2024) also view the EU as a global standard setter in the trade area. The authors interrelate OSA with the principle of technology sovereignty which should be guaranteed to serve the EU's positioning as a global standard setter. With the focus of OSA expanded from sovereign mission to economic resilience mission, technology sovereignty should be firmly insisted and is of great importance for value creation for the EU industries (Raza, 2021). More competent supply chain systems are required for the maintenance of the EU's industrial competitiveness (Raza, 2021).

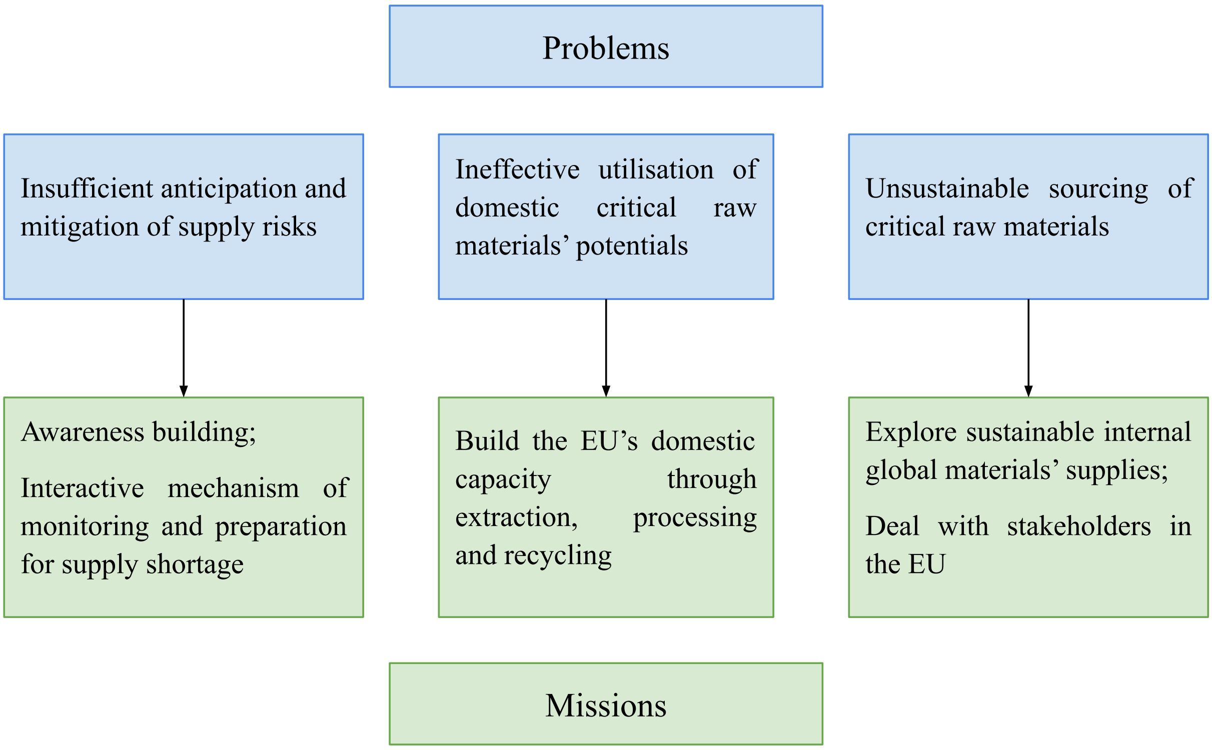
One of the ten pillars of OSA is securing and diversifying the supply of CRMs. Self-sufficiency of CRMs can increase the EU's bargaining power on CRMs' sourcing in the global market and reduce the lead-time for EU manufacturers (Domnick *et al.,* 2023). Further development of the EU's CRMs' sourcing system should be more friend-shoring and reshoring within the EU region (European Commission, 2023e). Strategic international cooperation and partnerships are thought to be complementary but indispensable for the realisation of OSA. With the legislation of the Critical Raw Materials Act, the embedding of OSA in a legislated CRMs policy has finally been accomplished.

2.3.2. The Critical Raw Materials Act

The Critical Raw Materials Act is the first comprehensive regulatory framework for the management of critical raw materials with much more concrete measures for policy implementation to boost the EU industries (Hool, *et al.,* 2023). Before the legislation, CRMs policy lacked regulatory support. Even though CRMs issues were mentioned in many policies such as 'Green Industrial Plan' and a 'Net-Zero Industry Act', there was no regulated framework with concrete goals and lack of effective implementation measures, not to mention, a policy performance assessment system for implementation control, which could not motivate all Member States (Hool, *et al.*, 2023). Policy instruments were limited to options like public funding for R&D in mining, recycling, substitution (Hool, *et al.,* 2023). Right now, the CRMs Act has established the benchmarks of policy implementation, the next step will be to define further evaluation methods and choose supporting programs to push forward (Hool, *et al.,* 2023).

The CRMs Act aims to deal with 'insufficient anticipation and mitigation of supply risks, underutilisation of domestic CRM potential, and unsustainable sourcing of CRMs' (Hool, *et al.,* 2023). The solutions to the three points are: 1)risk awareness and participation for monitoring, 2)an increase of the EU's domestic capacity through extraction, processing and recycling, 3)and the construction of external partnerships, in which the capabilities of leading firms in each industry should be very well explored (Hool, *et al.,* 2023). In addition, the concerns from environmental stakeholders should be adequately dealt with.

The comprehensive goals of the CRMs Act require a high degree of participation from Member States to the EU as a whole. Budgets, staff and equipment are indispensable for policy implementation (Rieker and Giske, 2024). For the EU Strategic Projects, coordinated financing and financial risk management are necessary (Hool, *et al.,* 2023). Executive enforcement and workforce, detailed implementation process, and collaboration among investors, companies and governments will be very important to push the policy forward (Hool, *et al., 2*023).



Graph 1: The problems and missions of the Critical Raw Materials Act

It should be mentioned that the regulatory power of the CRMs Act has an impact only within the internal market and is less likely to have coercion on global stakeholders and third parties (Rieker and Giske, 2024). In fact, before the release and legislation of this regulatory framework, the EU government would rather leave the CRMs issues to international market mechanisms (Hool, *et al.,* 2023). It is not about 'imposing rules on third parties, but rather about the third party willingly adopting them' (Bradford, 2020, in Rieker and Giske, 2024, p.50). It should not be underestimated that the stakeholders behind the CRMs Act are complex, which include the EU's mining and processing industry, manufacturing industry and original equipment manufacturers (OEMs), recycling industry, national governments as well as Non-EU actors and so on. These stakeholders are confronted with opportunities and challenges brought by the CRMs Act. However, it is not guaranteed that opportunities can overwhelm challenges for each stakeholder. Furthermore, the opportunities and challenges can not be separately interpreted. For example, it is true that the manufacturing industry and OEMs reduce the supply risks by domestic production and new strategic partnerships, but additional costs for compliance can not be avoided (Hool, *et al.,* 2023).

2.3.3. Supply chain and value chain management

'Supply chain management is the management of upstream and downstream relationships with suppliers and customers to deliver superior customer value at less cost to the supply chain as a whole' (Christopher, 1998 in Holweg and Helo, 2014). The transformation of raw materials to products is an integrated process which involves materials suppliers, manufacturers, distributors and customers (Marthur, *et al.,* 2018). In addition, supply chain not only streams materials and products, but also streams finance and information. Good coordination of actors, relationships, resources, an adequate match of supply and demand contribute to operational efficiency, and finally, to value creation (Turhan and Vayvay, 2009; Simatupang et al., 2004). The aim of SCM is to acquire the right product, at the right price, at the right time, where suppliers' integration plays a vital role to guarantee product availability and optimise order cycle (Marthur, et al., 2018). The realisation of this aim requires effective and efficient supply chain management.

In respect of the healthcare supply chain, Banomyong and Supatn (2011) pointed out that the transformation from materials to products and service is longer and complexer and should be carefully considered. The end customers in the healthcare supply chain are not those customers who purchase the final products such as hospitals, but should be consumers who are handled by the healthcare service providers. The transformation from materials to products and service is longer and complexer. In this situation, costs can be reduced through better coordination and collaboration among suppliers, intermediaries, and customers.

The performance of the supply chain is influenced by risk, which can happen at any process. Risk is generated from uncertainty. Risk may result in inefficiency and ineffectiveness which may bring down the overall performance in the supply chain, when resilience and flexibility of the supply chain is too weak to respond to the challenges (Heckmann *et al.,* 2015, in Rehman and Ali, 2022). A lack of preparedness for risks such as insufficient coordination in the supply chain may aggravate the severity of supply chain problems (Vecchi and Cusumano, 2020 in Rehman and Ali, 2021). Global supply chain is confronted with more complex variables and higher exposure to uncertainty than local supply chain, yet, there are also opportunities to leverage the resilience capabilities in the supply chain through reinforced networks with integrated partnerships (Li et al., 2019 in Rehman and Ali, 2022). Generally speaking, the main reason for healthcare supply chain disruptions is supplier-related risks which concern possible imports disruptions, ineffective information-sharing mechanisms and supplier failure (Moktadir et al., 2018).

A resilient supply chain should be able to adapt its capability to predict, identify, mitigate risks and maintain control over various variables involved (Ponomarov and Holcomb, 2009 in Rehman and Ali, 2022). A resilient supply chain should also have the flexibility to mitigate losses and recover from damages caused by realised risks (Bradaschia and Pereira, 2015, Jabbarzadeh and Sabouhi, 2018). Rehman and Ali (2022) discussed strategies for supply chain resilience in the healthcare industry based on a multi-criteria decision-making method. The starting point of the method is cultivation of risk resistance capability. The strategies of supply chain resilience cover multiple suppliers, geographical diversification, risk awareness, supply chain's agility and industry 4.0 (real-time data analytics). In addition, to mitigate the supply risks, collaborative planning and decision-making is important when possible(Rehman and Ali, 2022).

The perspectives of value chain management and supply chain management are different. Supply chain is 'an operational structure' designed for supply performance (Halldórsson, Hsuan and Kotzab, 2015; Matthias, 2013); value chain is 'a process architecture' which creates financial benefits in sequential steps by a set of firms (Porter,1985 in Matthias, 2013). To extend value creation strategies in the supply chain, Holweg and Helo (2014) recommended a combined and complementary perspective on supply chain management and value chain management. In the supply chain, the foremost consideration is that supply disruptions should be minimised, so that linear flows of information and materials can be efficient. The focus is the continuity of the flow in the supply chain. Whereas in the value chain, the focus is on the multi-information and materials flow in a single supply, distribution and retail chains. The focus is on the sharing of the flow.

The degree of complexity of the supply chain defines the complexity and dynamics of the value chain. A well-designed value chain architecture can boost value creation and supply chain operation (Hinrichs-Krapels et al., 2022).

'Values are created through the integration and coordination of supply, demand and relationships' (Simatupang et al., 2004; Wong et al., 2005, in Marthur, 2018). The value creation system is much wider and larger than the supply chain, where all the elements and components and mutual relationships are mapped. Holweg and Helo (2014) define value chain architecture as 'a conscious design of the network structure consisting of suppliers, manufacturers, distributors and customers in order to maximise the value creation for the focal firm'. The 'value chain architecture' refers to value provision, operations footprint, risk management, order fulfilment strategy and buffering mechanism.

Wan and Wu (2017) conducted a quantitative study about value distribution and vertical spillovers in value chains and analysed the phenomenon of how suppliers in emerging economies seized the opportunities of trade liberalisation and MNCs' internationalisation to accumulate international business experience. Specifically, the study found out that the speed of supplier's capability development is deeply impacted by its relationship with its buyer. The result implied that on one side, firms can be greatly influenced by uncertainty in the supply chain; on the other side, firms can influence the supply chain.

In respect of CRMs' value chain studies, Bartl *et al*.(2018) conducted a value chain analysis of substitutes and recycling of cobalt, niobium, tungsten and yttrium. The research pointed out existent problems and challenges in CRMs' substitutes and recycling process, e.g. relatively higher costs, the lack of material's performance, and inefficiency or unworthiness of recycling. The research also mentioned that the EU's reserves of CRMs are very low or even none and the optimised choice of which is the diversification of global suppliers of pertinent materials. The European COST Action CA15102 supported by the European Cooperation in Science and Technology in 2015 suggested that substitutes for CRMs could be encouraged, when they do not harm the performance (Bartl *et al*., 2018). However, it has not been proven whether it is realistic in a highly-competitive business environment.

The decision making for the global value chain is not only about profit generation, but also sustainability and risk management (Gereffi *et al.*, 2021). There are many factors which are important for the construct of the global value chain, for example, geographical distribution of resources, technological push, upgrading of suppliers, external risks such as policy uncertainty (Zahoor *et al*., 2023). In addition, technical processing requirements of specific materials and the need for cost efficiency make manufacturers stick to the existing partnerships. Moreover, the uneven distribution of the value created across the supply chain attracts global suppliers to improve their production capabilities to retain more tasks in their own land or region when possible (Gereffi *et al.,* 2021), which can exert pressure on buyers when uncertainty in the global environment significantly increases.

2.4. Critical raw materials and The Critical Raw Materials Act

2.4.1. Definition of critical raw materials

Since the first list of CRMs was published in 2011, the list has been renewed four times. Till the release of the fifth list, thirty-four types of CRMs are identified in the Critical Raw Materials Act (Annex I of the CRMs Act). The screening of raw materials are divided into groups based on their different properties. For industrial application, raw materials can be grouped into industrial and construction minerals, iron and ferro-alloy metals, precious metals, rare earths, other non-ferrous metals, bio and other materials (Grohol and Veeh, 2023). The identification of CRMs is based on the criticality assessment of the economic importance and supply risk of a raw material for the EU (Article 4 of the CRMs Act; European Commission, 2023c).

Critical raw materials in the CRMs Act refer to the raw materials of high economic importance for the EU and of a high risk of supply disruption at the same time. Due to the high geographical concentration of CRMs' reserves in non-EU lands and the lack of good, affordable substitutes (European Council, 2024b). Economic importance refers to 'the value added during the process of manufacturing to the final products' (European Council, 2024b). The technical and cost performance of substitutes are also calculated into economic importance. The higher the value added to the final products and the lower the possibility of application of substitutes, the higher the economic importance. Supply risk refers to 'import reliance which takes concentration of primary and secondary supply of CRMs', which relates to the extraction, processing and recycling stages (Grohol and Veeh, 2023).

CRMs include an amount of rare earths and non-rare earth materials. Half of CRMs are rare earths. Rare earth elements refer to the 15 elements in the lanthanide series and 2 transition elements (scandium and yttrium) in the periodic table. The criticality of rare earth elements to the EU strategic industries is significant, especially the materials used in permanent magnets (neodymium, praseodymium, terbium, dysprosium, samarium, gadolinium, cerium) and yttrium for laser technology and other REEs for radiology because of their optical properties (Grohol and Veeh, 2023).

Non-rare earth materials are another important component in the CRMs Act. Many non-rare earth elements are of strategic importance because of their unique application in the EU strategic industry like defence, digital, green, energy industry and other high-tech manufacturing. It should be mentioned that non--rare earth elements are not definitely critical in all forms of existence and the form of existence of element is an essential criterion for its recycling. For example, titanium metals rather than titanium pigment is critical and titanium pigment can not be turned into titanium metals.(Grohol and Veeh, 2023).

The criticality of a specific CRM may not be constant. Due to the changeable supply-demand relationships and the value added to the final products, the result of the criticality assessment can be different over time (Grohol and Veeh, 2023). However, the criticality of most rare earth elements is constant because of the relationship between the demand and production capacity, regardless of the wide distribution of reserves worldwide (United States Geological Survey, 2024).

2.4.2. The importance of critical raw materials

The EU consumption on CRMs has been largely increasing in the last decades and will still be increasing in the future because of the demand created by emerging and improved technologies and industrial transitions (Tercero, et al., 2021). According to the updated EU Industry Policy, 'EU industry accounts for more than 20% of the EU economy and 80% of the EU's goods exports' (European Council, 2024c). Industrial development is highly dependent on CRMs. Take REEs as an example, REEs' innate attributes like high malleability and ductility as well as their magnetic and luminescent properties which can enhance the performance of other metals and make products smaller and lighter (Rare Element Resources Ltd., no date). Thus, the application of REEs is crucial for the EU's high-tech industry to maintain its core competitiveness in the global market. The continuously extended lists of CRMs by the CRMs Act have proven the increasing indispensability and criticality of CRMs to the EU industries.

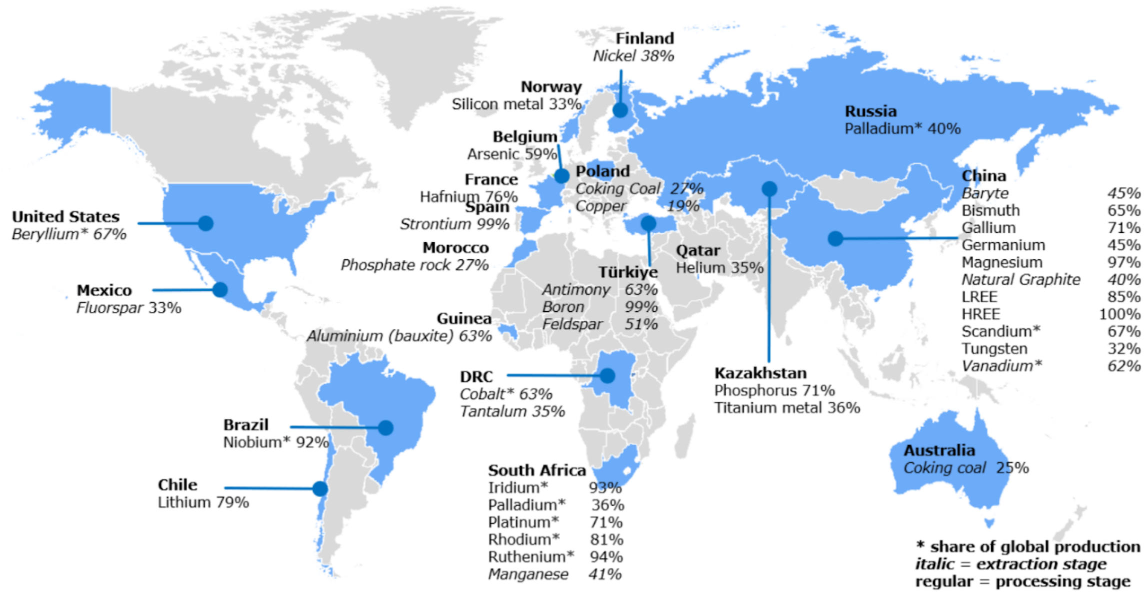
However, critical raw materials are exhaustible. Take REEs as an example, 'even though rare earths are relatively abundant in the Earth's crust, their minable concentrations are less common than most other mineral commodities' (United States Geological Survey, 2024). In recent years, the demand of the mining production has exceeded the amount of newly-found reserves. The global mine production of rare earths and estimated reserves in 2016 are 132,000 tonnes and 120,000,000 tonnes (Gambogi, 2017 in Bartl, *et al.,* 2018). In 2021, the mine production rose up to 243,300 tonnes with a sharp decrease in reserves to 115,820,000 tonnes (LePan, 2021, in Erust, et al., 2023). In 2023, the mine production rose continuously, largely to 350,000 tonnes (United States Geological Survey, 2024), however, the world reserves fell to around 110,000,000 tonnes even though there were newly-found reserves (Statista, 2024a). In addition, discovery of new mining reserves cannot immediately become extractable and processible because of the geological situation and technical limitations.

Moreover, there are many potential or existent confounders of supply such as prohibition of mining, embargo on export, less effective transportation facility and planning in some countries, ban on materials processing knowledge transfer due to market competition. For example, Special Administrative Measures (Negative List) for Foreign Investment Access (2020) by the Chineses Government stated that 'foreign investment in exploration, mining and beneficiation of rare earth, radioactive minerals and tungsten shall be prohibited.'

Country	Mining production of rare earths (tonnes)	Reserves of rare earths (tonnes)
Australia	18,000	5,700,000
Brazil	80	21,000,000
Burma	38,000	-
Canada	-	830,000
China	240,000	44,000,000
Greenland	-	1,500,000
India	2,900	6,900,000
Madagascar	960	-
Malaysia	80	-
Russia	2,600	10,000,000
South Africa	-	790,000
Tanzania	-	890,000
Thailand	7,100	4,500
United States	43,000	1,800,000
Vietnam	600	22,000,000
World total(round)	350,000	110,000,000

Table 2: World mining production and reserves of rare earths[1]

[1] Source: United States Geological Survey (2024) Rare earths - Mineral Commodity Summaries.



Source: "European Commission, Study on the Critical Raw Materials for the EU 2023– Final Report"

Graph 3: The share of EU's main sourcing countries of CRMs

For the EU industries, a large amount of CRMs are sourced outside the EU. For example, according to the EU SCRREEN database (SCRREEN, 2020b), the EU's reliance on China's heavy rare earths is 99% with an exemption of scandium sourced from the UK. Thompson (2022) indicates that 95% of high-strength rare earth permanent magnets are manufactured in China. Chinese companies have integrated rare earth mining, processing, metal production and magnet manufacturing (Thompson, 2022). According to the World Integrated Trade Solution, in 2023, the European Union imported 492,052 kilos of rare-earth metals including scandium and yttrium which have the value of nearly 8.9 million US dollars; At the same time, a value of 2.5 million US dollars of rare-earth metals including scandium and yttrium was exported; The demand on REEs for the EU's own industrial manufacturing valued roughly 6.4 million US dollars; The import has been reduced by 1,5 million US dollars in comparison to the figure in 2018 (World Integrated Trade Solution, 2023a). Considering China's dominance on the REEs world market, the reduction is significant. From 2018 to 2023, the EU has cut a quarter of REEs import from China and enlarged its REEs import from Turkey, Israel, the United Kingdom, Japan and begun to develop access to REEs resources in Canada and Thailand.

Dependencies result in supply chain vulnerability and set limits of manufacturing activities (European Parliament Research Service, 2022b). Price of a critical raw material with sharp growth can make it harder to get access to the raw materials, especially when unforeseen external environment changes, for example, policy changes in an important third country or increased political tensions in a region involving the sourcing country, the negative effect of EU's dependencies will emerge in involved industries. (Tercero, *et al.,* 2021, European Parliament Research Service, 2022b).

For the EU promoting diversification of CRMs' global sourcing, it is good to know that more countries are joining this world competition for mining and refinery business, for example, Australia, Vietnam, India, South Africa, Tanzania, Burma, Madagascar (United States Geological Survey, 2024). In addition, Greenland, which has a geographical proximity to the EU continent and has deposits in yttrium, scandium, neodymium and dysprosium (Innovation News Network, 2023).

The importance of critical raw materials is reflected in their influence on economic activities as the foremost resources for industrial manufacturing. The influence of the industrial production inefficiency can be dispersed to many other industrial sectors (Rehman and Ali, 2021). For example, inefficiency in alloys' production using CRMs will delay the delivery of products to the healthcare devices manufacturer who uses the products as necessary components for devices. The delay of medical equipment delivery will increase the waiting time of the patients and delay the diagnostics and treatment service provided by medical service providers, which increases the pain-suffering and mental suffering of the patients and in extreme circumstances risks the patients' life. Even for the medical products dealing with beauty and care, the delay of which still can cause a real-time unsatisfied customer experience and a decline in sales and profitability, which harms the value chain. Furthermore, products supported by newly-introduced improved technology have better performance which is guaranteed by the application of unsubstitutable materials. Supply disruptions will affect the wide promotion of new products and interrupt the value creation process.

Name	Annual growth rate of production	EU CRM sourcing suppliers	Global CRM main sourcing suppliers	Import reliance of primary materials	Import reliance of refinery materials
Light rare earths elements (LREEs)					
Cer	9.7%	Russia (64%) China (18%) UK (4%)	China (68%) Australia (10%) USA (9%) Myanmar (8%)	100%	100%
Neodymium	10.3%	China (80%) UK (3%) USA (2%)			100%
Promethium	n/a				
Heavy rare earths elements (HREEs)					
Scandium	n/a	UK (98%) Russia (1%)	China (66%)	100%	100%
Yttrium	4.8%	China(100%)	China(100%)		
Gadolinium	10.2%	China (98%) Other non-EU (1%) UK (1%)	China (86%) Australia (6%) United States (2%)		
Terbium	9.1%				
Dysprosium	8.8%				
Holmium	3.7%				
Erbium	8.4%				
Thulium	3.8%				
Non-REEs elements					
Lithium	13.8%	Chile (78%) United States (8%) Russia (4%) Germany, Csechia, Spain, Portugal, Austria, Finland	Chile (44%) China (39%) Argentina (13%)	81%	100%
Beryllium	0.4%	n/a	United States (88%) China (8%) Madagascar (2%)	n/a	100%
Boron	-0.2%	Turkey (98%)	Turkey (42%) United States (24%) Chile (11%)	100%	70%
Magnesium		China (93%)	China (89%) United States (4%)	100%	n/a
Titanium	2%	n/a	China (45%) Russia (22%) Japan (22%)	100%	n/a
Vanadium	5.2%	China (55%) South Africa (22%) Russia (19%)	n/a	n/a	2%
Cobalt	7.3%	Congo DR (68%) Finland (14%) French Guiana (5%)	Congo (59%) China (7%) Canada (5%)	81%	1%
Nickel	5%	Canada (59%) South Africa (19%) USA (9%) Norway (3%)	Indonesia (26%) Philippines (14%) Canada (8%) Australia (8%)	31%	75%
Baryte	-2.4%	China (38%) Morocco (28%) Other EU (15%) Germany (10%) Norway (1%)	China (38%) India (12%) Morocco (10%)	74%	n/a
Tantalum	7.3%	Congo, DR (36%) Rwanda (30%) Brazil (13%)	Congo, DR (33%) Rwanda (28%) Brazil (9%)	99%	n/a
Tungsten	3.3%	Austria Portugal	China (69%) Vietnam (7%)	21%	80%

		Spain	United States (6%) Austria (1%) Germany (1%)		
Rhenium	0.7%	n/a	Chile (49%) USA (19%) Poland (15%)	n/a	92%
Platinum group metals	-0.2%	n/a	South Africa (84%) - iridium, platinum, rhodium, ruthenium Russia (40%) - palladium	n/a	n/a
Bauxite (aluminium)	4.3%	Guinea (64%) Greece (12%) Brazil (10%) France (1%)	Australia (28%) China (20%) Brazil (13%)	89%	58%

Table 3: The EU industries reliance of critical raw materials[2]

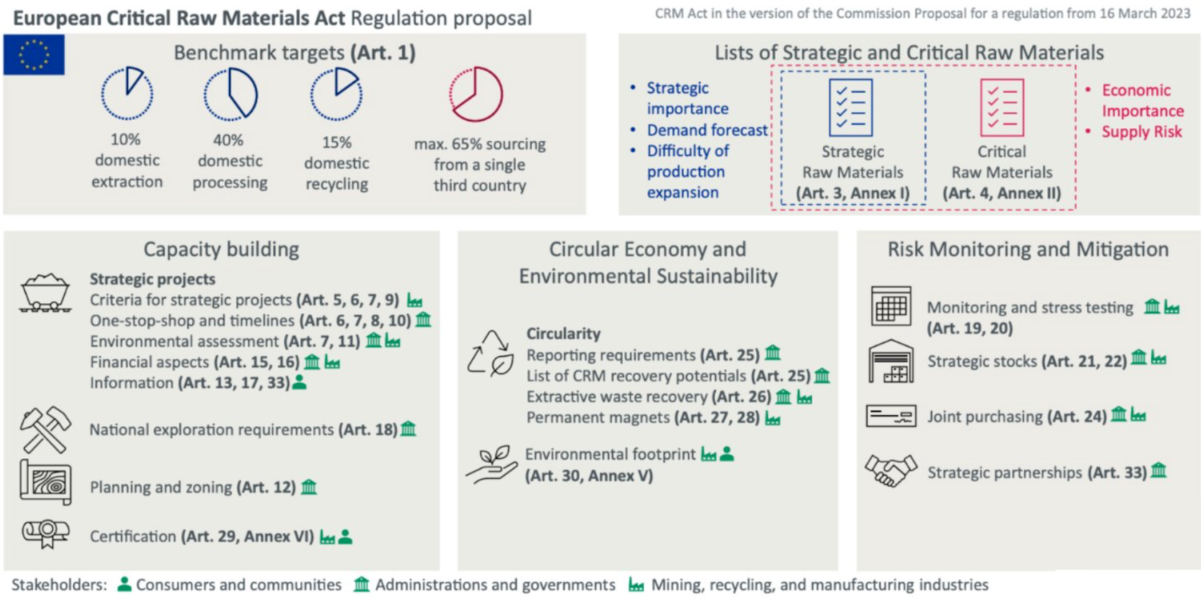
Red: extraction and processing outside the EU.
Orange: extraction outside the EU.
Green: extraction and processing are basically available within the EU

2.4.3. The content of the Critical Raw Materials Act

Based on the objectives to solve the problems of high dependencies of CRMs' supplies from outside the EU, the CRMs Act divides the tasks into three parts:1) risk monitoring and mitigation, 2) capacity building and 3) circular economy and environmental sustainability (European Commission, 2023c; Hool, *et al.*, 2023).

The EU Critical Raw Materials Act set a series of goals on mining, processing and recycling by 2030. These benchmarks evaluate domestic capacities and the degree diversification in the CRMs supply chain: 'the EU should extract at least 10% of the raw materials it consumes, the EU should produce, through processing, at least 40% of its annual consumption of strategic raw materials 40%, and through recycling waste, the EU should be able to produce at least 25% of its annual consumption.' (Article 1 of the CRMs Act). Furthermore, an important criterion is that 'the European Union's annual consumption of each strategic raw material at any relevant stage of processing from a single third country should be no more than 65%' (Article 1 of the CRMs Act), which indicates the EU’s determination to reduce risks generated from potential supply disruption from a single country on the EU's manufacturing industry.

[2]Source: European Commission's Raw Materials Information System, Royal Society of Chemistry (UK), 'Critical Raw Materials Resilience: Charting a Path towards greater Security and Sustainability'.



Graph 2: An illustration of the EU Critical Raw Materials Act[3]

Pillar 1: Diversification of strategic partnerships with global suppliers

Improving global partnerships is important for the EU to enhance its CRMs' value chain. Strategic partnerships can lead to 'coherence and potential synergies between EU Member States' bilateral cooperation with relevant third countries and the actions carried out by the Union in the context of Strategic Partnerships' (Chapter 6 of the CRMs Act). The policy will be implemented on both the EU and Member States level.

The variety and flexibility of partnerships contributes to sustainable supply of CRMs and CRMs' products for the EU industry. 'Friend-shoring' including 'near-shoring' has a strategic function on the improvement of multilateral and bilateral international cooperation relations (Gstöhl and Schnock, 2024). To build and/or develop global partnerships, the EU began its 'active raw materials diplomacy' in 2008. In the last two decades, continuous efforts on multilateral fora like G7 and G20, bilateral relations and bilateral FTAs with like-minded third countries, policy dialogues with third countries, the EU is gaining more access to critical raw materials (Gstöhl and Schnock, 2024). The diversification of global partnerships on CRMs emphasises openness of the OSA principle by positioning the EU as a constructive partner in relationships and a co-founder for cooperation (Gstöhl and Schnock, 2024; Findeisen and Wernert, 2023).

[3]Source: Hool, A., Helbig, C., Wierink, G. (2023) Challenges and opportunities of the European Critical Raw Materials Act.

The performance of diversification of global suppliers in the CRMs Act will depend on several factors. First, It will depend on the EU's funding for infrastructure investments in third countries through programs like Global Gateway Strategy (Findeisen and Wernert, 2023). The CRMs Act 'does not adequately incorporate geoeconomic risks in the selection criteria of these projects' (Gstöhl and Schnock, 2024). For instance, there are export restrictions on CRMs introduced by countries such as China, India, Argentina, the Democratic Republic of Congo, Senegal, Vietnam and Kazakhstan. It is important for policy implementers to anticipate supply disruptions resulting from policy changes in other countries. Second, the strengthening of supply chains and the diversification of CRMs' sourcing need coherent and synergistic approaches (Gstöhl and Schnock, 2024; European Commission, 2024). To reach out and integrate all potential and extant partners, the function of expanded networks like a critical raw materials club involving resource-rich countries should be of help (European Commission, 2024). Furthermore, a comprehensive framework of bilateral and plurilateral agreements should be further developed on the CRMs-related issues (Gstöhl and Schnock, 2024). What's more, duty suspensions and tariffs can also have an impact on CRMs' import to the EU (European Commission, 2024). All of the issues are to be dealt with by the government rather than by the industrial participants. To what extent the efforts outside the EU can contribute to European firms' diversification of suppliers base, the answer is open for the firms.

Another highlight in the policy is the voluntary joint purchasing of strategic raw materials from outside the EU. The European Commission 'shall set up and operate a system to aggregate the demand of interested undertakings consuming strategic raw materials in the Union and Member State authorities' (European Commission, 2023c). Rather than a purchasing system, the system includes stocks' checking and materials purchasing. It is to better leverage the market of the imported CRMs. The possibility of the joint purchasing becoming compulsory still exists (Gstöhl and Schnock, 2024). However, not all the industries will be highly involved in joint purchasing. The impact of joint purchasing depends on the amount of application of a material in an industry.

Nevertheless, the EU has much space to play on in its global supply chain of CRMs. The methods to enhance the supply chain are new partnerships and knowledge transfer. Take the heavy rare earth material yttrium as an example. Currently, the EU's supply of heavy rare earths is almost exclusively from China. In fact, China has only about 41% of the global reserves of yttrium, followed by Australia and India. It implies possibilities for diversification of rare earths sourcing from countries outside the EU in the future. Or, the EU could fill knowledge gaps by cooperation with third countries in the value chain. For example, Malaysia has built its own mining facilities with a stable increase in export of raw rare earths, however, the country lacks core knowledge about processing and refining technologies (Toeh, 2024). As processing and refining technologies are core competence and critical know-how for countries who own them, similar cases like Malaysia could be viewed as an opportunity for the EU, supposing that the EU has the know-how for rare earths processing.

Pillar 2: Establish regional capacity for CRMs' mining and processing

According to Article 2 of the CRMs Act, 'Union extraction capacity' refers to 'an aggregate of the maximum annual production volumes of extractive operations for ores, minerals, plant products and concentrates containing strategic raw materials', and 'Union processing capacity' refers to 'an aggregate of the maximum annual production volumes of processing operations for strategic raw materials, excluding such operations that are typically located at or near the extraction site, located in the Union'.

The EU's dependencies on third countries at the mining and processing stage of CRMs are high, thus, capacity building is a very important mission. Growing geopolitical uncertainties and the threat of raw material shortages make investment in mining and processing of rare earths within European countries more necessary as well as attractive than before.

The acceleration of permission procedures and planning of financial support aim to attract new participants to enrich the EU Strategic Projects on critical raw materials issues. An extraction project should be assessed by authorities within twenty-four months and a processing project within twelve months (European Commission, 2023c). Member States are encouraged to set national programs to push the implementation forwards (Gstöhl and Schnock, 2024). The approaches of the CRMs Act sought to deal with the financial risks for capacity building activities through risk sharing mechanisms involving Member States, EU funding and financial institutions, and companies (Findeisen and Wernert, 2023). A successful example is the expansion of a processing plant mainly for neodymium and praseodymium in France by the Belgian Chemical Group Solvay (Mook, 2023). The company has rebuilt its facilities on the old site and established its value chain of rare earth magnets production and recycling in the EU (magneticsmag, 2024).

However, there are still many challenges which should be conquered. Findeisen and Wernert (2023) view Strategic Projects as time-consuming and high-risk for investment. The business might only involve a limited number of large companies which are able to support the project financially and technologically (Findeisen and Wernert, 2023). Furthermore, setting a timeframe for a construction project is also important for investors (Righetti and Rizos, 2023). Righetti and Rizos (2023) also point out that the data about CRMs reserves and minable potentials may not be comprehensive and mining projects need more support from further exploration and monitoring. In addition, whether permitting procedures for extraction and processing projects will be quickly accomplished, is dependent on each Member State’s decision (European Commission, 2024).

Pillar 3: Promote recycling and substitutes for CRMs

Recycling of CRMs aims to realise more efficient consumptions of CRMs; substitutes for CRMs are for an optimal choice of cost and performance for manufacturers. Recycling and substitutes can bring great benefits to the CRMs-intensive high-tech industries which have an increasing demand for CRMs in the near future. Recycling is an important source of secondary raw materials and can mitigate supply risks of critical raw materials in a greener way (Santillán-Saldivar, 2021). Substitutes are also an efficient way which can reduce negative environmental and social impacts brought by mining and processing of specific CRMs, for example, heavy rare earths.

The CRMs Act aims to contribute to a circular economy through well-organised looping flows of resource and product (Gstöhl and Schnock, 2024). Not only better recycling mechanisms for end-of-products will be launched and developed within industries, materials input will be of less weight and higher purity to guarantee performance. 'Longer product life-time via repairs, reuse or upgradability' is the trend for manufacturing in strategic industries applying CRMs (Gstöhl and Schnock, 2024).

The CRMs Act also mentions a possible way for recovery, which is 'recovery of CRMs from extractive waste' (European Commission, 2023c). The CRMs Act suggests recovery of the old mining sites which may contain CRMs’ resources. Demand for new mining can be to some extent mitigated through improved metal scrap management (Bartl et al., 2018). In fact, this idea is adaptable for both local and global supply chains, including recovery of CRMs from extractive waste in the EU as well as in third countries.

At this point, a particular example is rare earth materials. The reported recycling input rate of REEs in the EU is lower than 1% (SCRREEN, 2020b). However, it is estimated that in about ten years, it will be possible to recycle rare earths materials to satisfy a quarter of demand of rare earths magnets (Wayman, 2023). There is already research on profitable recycling of rare earths magnets, for example, pulling rare earths from discarded magnets and using microbes and bacterial acids to assist recycling of rare earth elements, or hydrogen-assisted recycling of rare earth elements (Wayman, 2023; Buckhardt, *et.al.*, 2023). In addition to recycling technology, more recycling-friendly and materials-sparing product designs will be equally efficient. (Wayman, 2023).

While diversification of suppliers focus more on third countries, capabilities building as well as recycling and substitutes are essentially based in the EU. The three pillars of the CRMs Act are complementary and encompass all available solutions to deal with CRMs' supply risks. The contribution of projects in the short term is likely to be limited due to the costs of input. Building a loop mechanism from extraction/processing to the end-of-life product stage may also face the challenges in stock management, input and output control, logistics, and so on (Righetti and Rizos, 2023). Nevertheless, as a supportive regulatory framework, the CRMs Act makes great efforts on reframing EU industries' value chain from the perspective of CRMs. The CRMs Actcreates opportunities for EU economic resilience.

2.4.4. Connection between the Critical Raw Materials Act and open strategic autonomy

Open strategic autonomy is an embedded principle as well as a comprehensive strategy which is unfolded in the terms of the CRMs Act. The OSA principle inspires CRMs' policy making. Gstöhl and Schnock (2024) divide the three pillars of the CRM Act relatively based on the connections with OSA: diversifying supply and global partnering (open, strategic, external), developing CRMs value chain in EU (open strategic, internal), fostering sustainable sourcing and promoting sustainability (strategic autonomy, internal).

Realisation of the CRMs Act is a prerequisite for 'achieving strategic autonomy while preserving open economy' and 'the EU's long-term capacity and freedom to react" (European Council, 2020; European Commission, 2023e). In the regulation, the core components - benchmark settings and strategic projects - are essential for the EU's capacity building (Hool, *et al.,* 2023). The European Council's final approval to the CRMs Act has recognised the comprehensive policy approaches and the clear benchmarks. The CRMs Act is expected to have a synergic effect with OSA on the handling of supply chain risks (European Council, 2024d).

Apart from the supporting relationship between the policy and the strategy, it is worth mentioning that the Critical Raw Materials Act and (open) strategic autonomy are connected in the EU industry policy, technological sovereignty and industrial value chain.

'Strategic autonomy should be improved through strong and diversified value chains and industrial competitiveness' (Council of the European Union, 2019). The accessible amount and guaranteed quality of raw materials are important for further manufacturing. Through diversification of the EU's supply chains and value chains, sustainable and efficient access to CRMs can be explored to guarantee product quality. At the same time, product innovation - the lifeblood of the value chain - can also be supported by a well-functioned CRMs' supply chain.

It is worth to mention, in terms of the meaningfulness of the CRMs Act and strategic autonomy in the EU industry policy, the European Council emphasises the supporting function of the CRMs Act in the autonomy of the EU industry, without paying attention to distinguishing the two terms 'strategic autonomy' and 'open strategic autonomy'. While the notion of open strategic autonomy in the CRMs Act is necessary, strategic autonomy is the essential concept for EU resilience.

The different expressions demonstrate the different focus of a single policy and a generalised political strategy. The CRMs Act can build a more solid material base for the EU industry and steer industrial practice (European Council, 2024d; Hool, *et al.,* 2023). Furthermore, the EU industrial competitiveness should and must in all circumstances be created and grasped in the EU's own hand. To some extent, the CRMs Act is the regulatory tool which requires OSA to reach a more generalised strategic autonomy expected by the European Council.

The situation is the same when it comes to technological leadership and value chains. The supply security of CRMs facilitates the EU's technological leadership and strengthens the value chains in key industries. CRMs are naturally not a core competence of industrial manufacturing. It is the advanced technology that demands CRMs and uses CRMs for industrial competitiveness, so that advanced technology can be truly commercialised and generates economic value. Both OSA and CRMs policy aim to 'activate EU's internal and external partners who are willing to cooperate and to sustain the EU manufacturing transition' (Henselmann, 2024).

Speaking of the industrial value chain, both OSA and CRMs Act are utilising dynamic factors to the supply chain in an increasingly dynamic global context. The empowerment of the European Commission in the last decade in EU economic and industrial affairs makes the EU capable of mobilising resources within the EU. Diversification of suppliers can impose the EU's values on like-minded countries and introduce more participants in the industrial ecosystem and realise dynamic equilibrium between suppliers and buyers. Furthermore, the increasing emphasis of materials and components recycling is a new source for value generation. As recycling infrastructure is located in the EU lands for transportation and monitoring reasons, the share of recycled CRMs applying in the supply chain can change the construct of the EU's is influencing the whole sourcing system. However, challenges do exist, when it comes to the particular standards for recycled materials in different strategic industries (Hool, *et al.*, 2023).

2.5. Critical raw materials in the EU's healthcare industry

2.5.1. The EU healthcare industry and critical raw materials

Healthcare industry includes 'all firms that are involved in the creation and delivery of medical products and services to customers' (Madanaguli *et al.*, 2022). Typical healthcare areas are pharmaceuticals, biotechnology, hospitals, medical device manufacturers and clinical research agencies. As CRMs are essential materials for medical devices manufacturing, changes in the CRMs' supply chain will have a direct impact on the medical devices manufacturers. The quality and volume of medical devices determines the quality of healthcare service. In addition, technological innovation and digitised systems for recycling can also have an influence on the healthcare industry.

The healthcare industry creates great value for the EU. The industry has a very well developed supply chain structure. Medical innovation and advanced manufacturing has built the EU’s competence in the global healthcare market. According to the World Integrated Trade Solution, the European Union exported medical diagnostic test instruments and apparatus worthed around 3 million euros in 2023 (World Integrated Trade Solution, 2023b).

Companies make decisions based on business interests. It is important for companies to take advantage of a favourable policy and avoid losses from an unfavourable policy. The aim of the CRMs Act is to create opportunities to enhance the EU‘s industrial competitiveness, while at the same time it raises challenges. Challenges should be dealt carefully with, even though there might be an erosion of profitability in the short term. It is believed that less dependencies on CRMs supplied from third countries is for the long-term benefits. Without sustainable and reliable CRMs sourcing, the value of technological innovation cannot be fully realised nor commercialised.

Like many other high-tech industries, the supply chain of the EU's healthcare industry also experienced complex global supply disruptions during the Covid-19 pandemics. Medical device manufacturing was also involved. Then, after the pandemics there is a strong bounce back in the medical devices sales. As there is a strong market prospect in the healthcare industry, the EU Global Health Strategy (2022) suggested leverage the industrial interdependencies between the EU and third countries, so that a deal of materials and technology between the EU and third countries can be achieved.

2.5.2. Application of critical raw materials in the EU's healthcare industry

The EU Global Health Strategy (2022) states that the supply of CRMs' resources is becoming more and more important for the healthcare industry. As open strategic autonomy has been generalised as an EU-wide ideation in the industrial sector, it has also become an emerging focus in health policy (Miró, 2023). CRMs and key components based on CRMs are of critical importance to healthcare manufacturing.

To highlight the contribution of CRMs to the EU's healthcare industry, this master's thesis identifies specific applications of pertinent CRMs used in the manufacturing of medical devices and medical equipment. Among all thirty-four CRMs, rare earth elements are widely used in "X-ray magnetic resonance imagery (MRI) contrast agents, nuclear medicine imaging, cancer treatment applications, and for genetic screening tests, medical and dental lasers" (Balaram, 2019; SCRREEN, 2020i); non-rare earth elements are used in superconducting magnets, electrical medical devices like hearing aids, heart pacemakers, orthopaedics and implantable medical devices, surgical instruments, diagnostics and testing, plating and many other medical treatments (SCRREEN, 2020a; SCRREEN, 2020c; SCRREEN, 2020d; SCRREEN, 2020e; SCRREEN, 2020f; SCRREEN, 2020f; SCRREEN, 2020g; SCRREEN, 2020h). However, because CRMs are widely applied in different EU industries and have low transparency in the global supply chain, it is hard to identify the share of CRMs applied in the medical device manufacturing.

Elements in the periodic table			Application of CRMs in the healthcare industry
			Light rare earths elements (LREEs)
58	Ce	Cer	Cerium-based oxide materials for use in biomedical devices (on research)
60	Nd	Neodymium	Nd: YAG-laser, Magnetic resonance imaging (MRI)
61	Pm	Promethium	Medicine, promethium beta therapy
			Heavy rare earths elements (HREEs)
21	Sc	Scandium	X-ray, lasers
39	Y	Yttrium	All types of YAG lasers
64	Gd	Gadolinium	Magnetic resonance imaging (MRI), industrial X-ray fluorescence
65	Tb	Terbium	Imaging: positron emission tomography (PET) and single photon emission computed tomography (SPECT)
66	Dy	Dysprosium	Arthritis therapy
67	Ho	Holmium	Ho:YAG laser
68	Er	Erbium	Er:YAG laser
69	Tm	Thulium	X-ray
70	Yb	Ytterbium	Yb:YAG laser
			Non-REEs elements
2	He	Helium	Radiology and microscopy
3	Lii	Lithium	Superconductors for MRI, lithium-based battery
4	Be	Beryllium	Beryllium folie used in medical radiography
5	B	Boron	Medecine, drug design and drug discovery
12	Mg	Magnesium	Bone density scanner, X-ray scanners, etc.
22	Ti	Titanium	Cardiovascular, dental implants, joint replacement, surgical instruments
23	V	Vanadium	Medicine
27	Co	Cobalt	Medicine, implantable medical devices, radiotracer for radiotherapy, detection of brain and lung metastases (efficient than MRI)
28	Ni	Nickel	Plating for medical devices and implants, drug manufacturing
31	Ga	Gallium	Positron emission tomography (PET)
38	Sr	Strontium	Bone tissue metabolism in osteoporosis treatment
41	Nb	Niobium	Superconducting electromagnets for MRI
56	Ba	Baryte	Special X-ray tests on the intestines and colon
72	Hf	Hafnium	Osteogenic devices, Hf-based CT-involved contrasts for tissue imaging or cancer diagnosis
73	Ta	Tantalum	Advanced surgical implants, implantable medical devices
74	W	Tungsten	Transport and containers for radioactive materials
75	Re	Rhenium	Diagnostics
78	Pt	Platinum	Plating for medical devices and implants

Table 4: Application of critical raw materials in the healthcare industry

It should be mentioned that in medical diagnosis and treatment, supply disruption of CRMs might lead to the delay of manufacturing and delivery. Then, it might further lead to the delay of diagnosis or misunderstanding when the healthcare service provider uses other devices as an alternative. One example is cobalt isotopes which are effective in detecting brain and lung metastases, as well as locating tumours. In addition to general imaging devices, cobalt isotopes are essential in detecting damage to the brain from a stroke or traumatic injury when traditional methods are not able to visualise the damage (Cobalt Institute, 2021). Insufficient supply of a required rare earth product or the use of a substitute will cause inefficiency and even undermine competence of the products in the global market. Another examples could be the important radionuclides for medical use which are in their specific isotope form like yttrium-90 (for cancer therapy), cerium-144 and promethium-147 (for measuring devices), gadolinium-153 (for X-ray fluorescence) and ytterbium-169 (for portable X-ray source), which cannot be easily replaced by substitutes (Institut für Seltene Erden und strategische Metalle AG, no date).

Many CRMs are very unique for pertinent medical devices to achieve the ideal performance and it can be hard to find substitutes for them. What's more, rare earth elements can not be easily substituted by another type of rare earth elements. Furthermore, the same rare earth element can have various isotopes, which means that the isotopes can not replace each other, even after recycling. Some examples could be the important radionuclides for medical use which are in their specific isotope form like yttrium-90 (for cancer therapy), cerium-144 and promethium-147 (for measuring devices), gadolinium-153 (for X-ray fluorescence) and ytterbium-169 (for portable X-ray source), which cannot be easily replaced by substitutes (Institut für Seltene Erden und strategische Metalle AG, no date). Moreover, even if an isotope could be transformed to another isotope, mining ores might be more efficient than transforming.

In addition, it should not be forgotten that based on the medical devices' size, weight and function, the input of pertinent CRMs in manufacturing should be different. Apart from the quantity of input of pertinent CRMs, the requirement for the components made by CRMs is strict and should be precisely formed for medical devices. Last but not least, apart from primary raw materials, production of secondary materials and key components is also of strategic industrial importance.

2.5.3. Characteristics of the application of critical raw materials in the EU's healthcare industry

CRMs are important materials for the medical manufacturing to improve the performance of medical devices and the service quality by healthcare providers. The addition of CRMs into the production process of large devices is complex and intransparent. In the supply chain of CRMs to healthcare manufacturing, there are some issues that should be notified.

First, a specific type of component made from the same rare earths materials can be found across the healthcare industry. Such a component is not only fit for one type of machine or product, but serves many different types of machines and products. For example, bio-compatible ultra-thin grade-1 titanium can be found across the medical industry, from advanced diagnostic, laboratory and surgical equipment to prosthetics, implants, drug delivery systems and radiation shielding. The high compatibility of a specific component implies that the supply disruption of a single component will lead to a supply disruption of production of many different devices.

Second, there is a need for medical devices with better biocompatibility, ultra-thinness, precise thinness and longer life cycle. Such advantages are adding more and more value to the medical devices manufacturing (Arnold Magnetic Technologies, no date). There is also a trend of research on application of immunomodulatory, antimicrobial, antimicrobial, safe and non-ferromagnetic materials (Qin, 2024). The change of a material to another - usually from a non-rare earth element to a rare earth element - aims for better performance. A compromise for lower performance should not be encouraged in the healthcare sector. Even though the medical device manufacturer has a catalogue of available products ranked by quality and price, the range of variation is restricted by market competition and market trends.

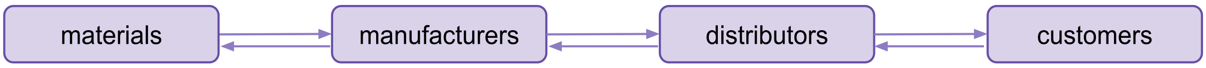
Third, high purity is not only a standard, but also guarantees high performance. For many medical devices, the higher the purity of the CRMs the less the amount of input is needed to achieve the same performance. As written by Kumari and Sahu (2023), 'the yield and purity can be in a trade-off situation'. Purity is necessary for a product with an extended life-cycle. Medical devices with longer lifetime can create more value than devices with lower sustainability and maintenance (Bartl, et al., 2018).

Fourth, for different applications, there are different types of substitutes with different collecting and recycling paths (Bartl, et al., 2018). Thus, recycled materials from other industries or machines can not be used in medical devices manufacturing. The recycling of

CRMs materials, especially REEs materials, is within the healthcare industry. In addition, as mentioned above, different isotopes from the same element can not be substituted by each other, which increases difficulties for the materials processing and recycling.

Last but not least, substitutes for a critical material can also be a type of critical material. Thus, whether the substitute solution is worth further application can not easily be concluded.

2.6. Supply chains of critical raw materials and medical devices manufacturing



Graph 3: The supply chain of critical raw materials

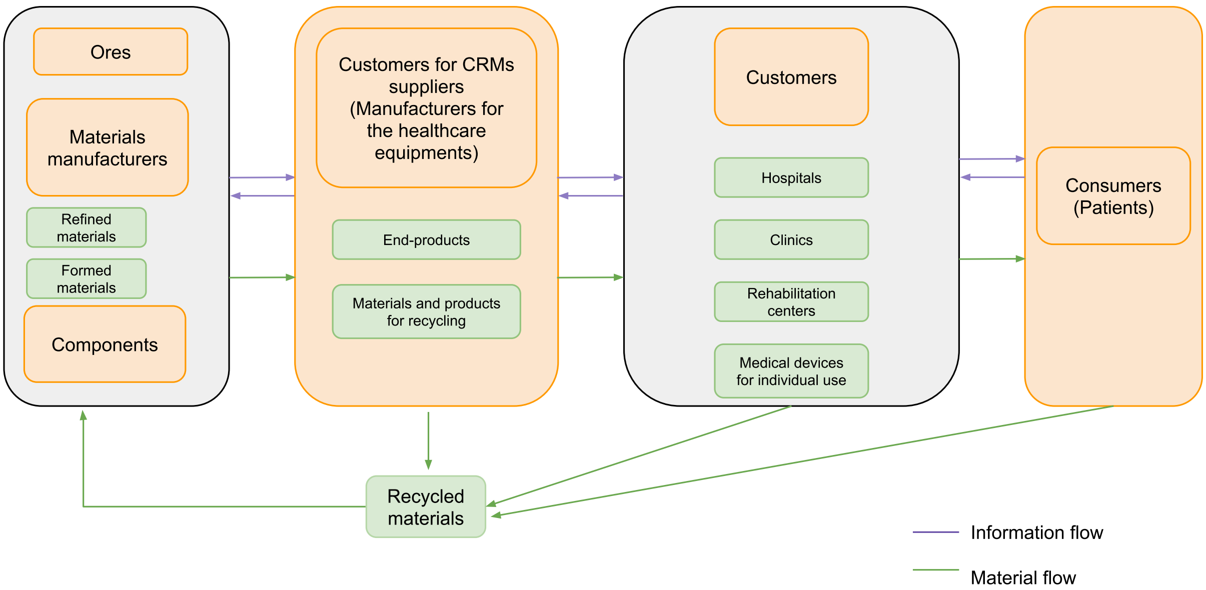
The supply chain of CRMs is an operational flow which flows on one side from materials providers to producers, distributors and customers. On the other side, the information and feedback flows back to from customers to distributors, producers and materials providers. The sharing of information can improve the efficiency of the supply chain and help the suppliers optimise their operations.

In the supply chain of critical raw materials, the materials suppliers are miners and processors of critical raw materials who have direct geographical access to the mines. They extract and refine materials to powders or crystals. Crystals are processed into wafers or as an additional material into a component. Components are delivered by the manufacturers themselves or by distributors to the customers, namely, the manufacturers for the end-product. Manufacturers have to adapt their supply chains and sourcing strategies, potentially facing increased costs and disruptions (Hool, *et al.*, 2023).

Graph 4: The supply chain of the EU healthcare manufacturing

The business-to-business (B2B) relationship between a manufacturer of healthcare products and its suppliers of critical raw materials and processed materials is a relationship between medical firms and non-medical firms (Madanaguli et al., 2022). The partnership is confirmed by the exsitence of the supply chain. They work together to deliver value of materials and high-tech products to the final customers and consumers in the value chain. From a business perspective, there should be an optimum number of participants (suppliers) for a particular purpose (Madanaguli et al., 2022).

The supply chain of the healthcare industry is characterised by a high level of customisation of products and services, high demand for participation of partner or consumer and high uncertainty (Pitta and Laric, 2004). Successful business depends on efficient flow of materials, information and finance. Many manufacturers are themselves distributors to deliver their products, for example, manufacturers for heavy and large medical devices. It helps to simplify the process, in which manufacturers have direct access to customers and provide consulting services. Based on customers' preference and demand, manufacturers can better organise production activities including the procurement of raw materials, processed materials and components.

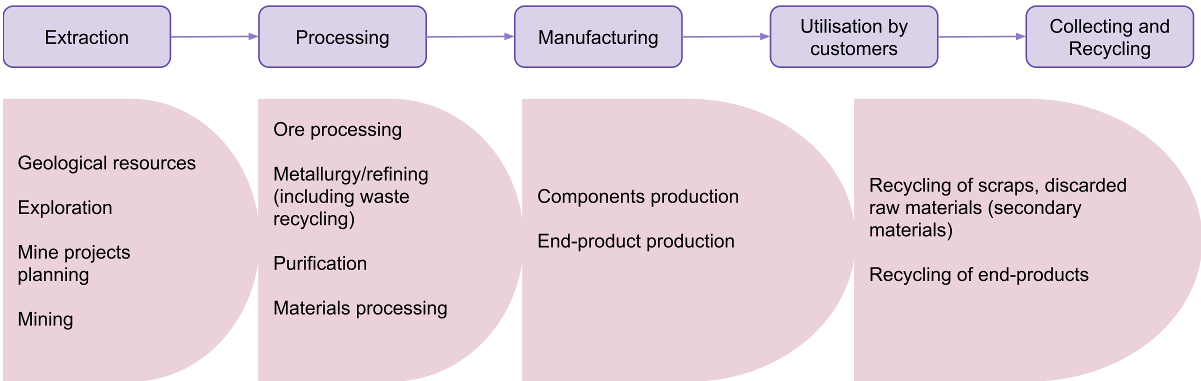


Graph 5: The complementary supply chain of the healthcare industry with a focus on critical raw materials

The interrelation of the CRMs' supply chain and the healthcare industry supply chain lead us to combine the Graph 3 and Graph 4 for further discussion. In the healthcare supply chain, the customers in the CRM's supply chain become the producers of healthcare equipment. If we focus on how CRMs are involved in the supply chain of the EU's healthcare industry, the recycling stage can be a highlight in the future, which not only involves the EU recycling business, but also may involve resources from third countries. Discarded medical devices and components as well as leftover materials from manufacturing can be the sources for secondary materials. These materials are expected to be recycled for the same use, until they are no longer recyclable.

2.7. Value chains of critical raw materials and medical devices manufacturing

The CRMs Act demands a comprehensive enhancement of 'the EU's critical raw materials capabilities along all stages of the value chain' (European Commission, 2023c). It means that the capabilities should be built or improved through extraction, processing, manufacturing, utilisation, collecting and recycling.



Graph 6: The value chain of critical raw materials

The addition of secondary materials is very important to optimise the value chain. Secondary materials that have been used, recycled and sold for use in manufacturing. In comparison to primary materials, secondary materials are less reliant on the search for new raw materials. The situation may exist, that byproducts from new ores can be taken and recycled as secondary materials for manufacturing (Innocenzi, 2014). However, regarding the amount of byproducts of a type of specific critical raw material, whether the method is cost efficient is not definitely defined.

Substitutions and recycling might result in higher cost or performance loss. Bartl *et al.* (2018) researched on the worldwide sourcing of cobalt, niobium, tungsten and yttrium and possible substitutions. Because different industries have their own quality standards of the application of critical raw materials, materials like tungsten are irreplaceable because of their high melting points of pure metals and unique performance. Moreover, Tercero et al. (2019) gave the example of barite and discussed the purity requirement for medical equipment manufacturing. Even though recycling could be profitable in the future (Deutscher Bundestag, 2022), to what extent can a recycled specific metal material meet industrial standards such as purity and toxicity for medical devices production? Furthermore, the characteristics of CRMs may result in difficulties which makes it not easy for extraction, refining, processing, transportation and recycling. For example, rare earths which have low gamma emission must be handled strictly according to safety regulations and interact only with certain transition elements (Elkina and Kurushkin, 2020).

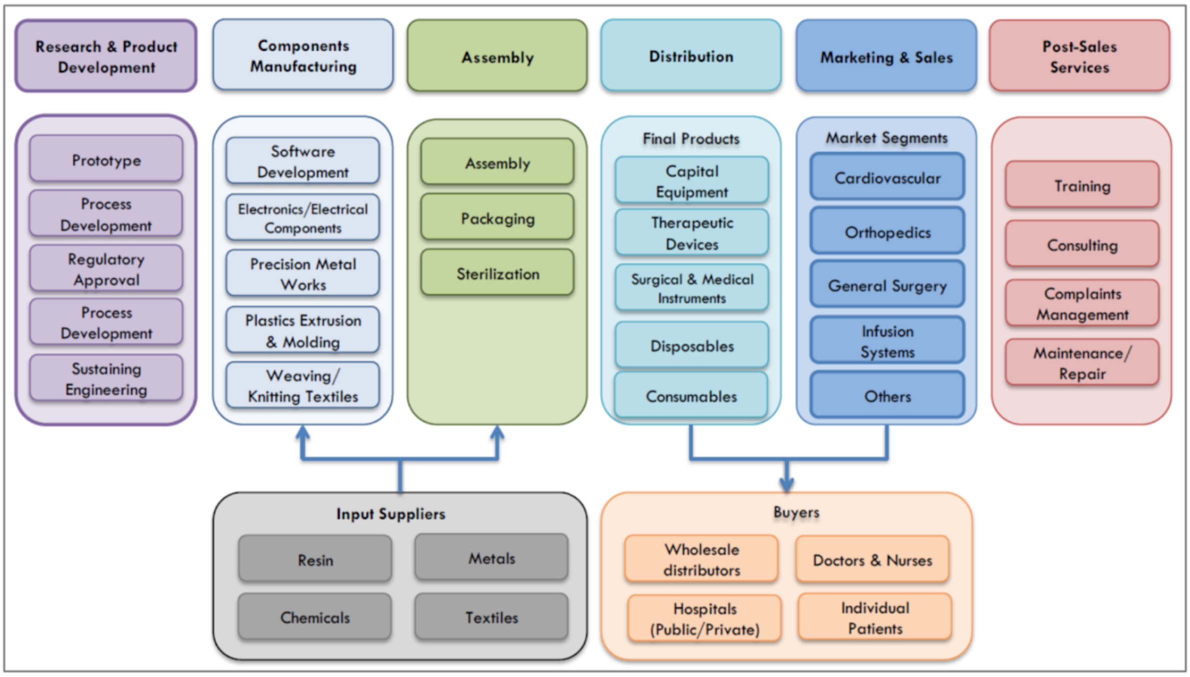
Value creation along the supply chain of CRMs needs further technological advancement.The efficiency of value creation can also be influenced by the recycling and usage of substitutes. However, it depends on the situation whether recycling or substitutes is a better way for a kind of critical raw material. For CRMs such as tungsten, the solution 'recycling' is much more efficient and has better potential in the future than 'substitutes'. It is the same with cobalt which can be recycled by reducing leaching from hard metal scraps and the technique is easy to master. For materials which have lower than 1% recycling rate, it is hard to judge whether research on 'recycling' or 'substitutes' should be prioritised.

Another problem for value generation through recycling is in which form do the materials exist in a product. For example, niobium is not recycled as pure element but niobium-containing steels and superalloys are recycled for the same alloy. This situation also causes problems in logistics management (Bartl*, et al.,* 2018). Another reason is the low utilisation concentration in a single alloy product, which makes separate handling not efficient (Bartl, *et al.,* 2018). That's why niobium end-of-life recycling in the European Union is 0.3% or more now.

A tricky question is that substitutes of a kind of critical raw material can also be another kind of critical raw material (Bartl, *et al.,* 2018). Bartl, *et al.*(2018) raised an example concerning a group of substitutes which includes tantalum, titanium, molybdenum, tungsten, and vanadium. The elements can be substitutes for each other under certain conditions, but they are all critical materials. Whether it is meaningful to use them as substitutes, can not be easily judged. Another relevant example is the CRMs for permanent magnets, namely, nickel, neodymium, cobalt, niobium, it is possible for the elements to substitute each other. It is possible to change a certain percentage of elements used in permanent magnets with substitutes. However, it depends on to what extent a sacrifice of product performance is permitted without a reputation decline of the products or a decline in the market share.

For different industries and industrial applications, there are different types of substitutes with different collecting and recycling paths (Bartl, *et al.,* 2018). This means, the end-product from one industry cannot be easily transformed to recycled materials for another industry. The fact is a challenge for value creation through recycling.

In addition, recycling and substitutes can have an impact on the price of CRMs. In the long run, affordability of CRMs is also very important for value creation. High supply dependencies imply weak reactions to the price volatility of a certain material. Having a sustainable supply of CRMs doesn't mean absolute efficiency in the value chain.



Graph 7: The value chain of the EU healthcare manufacturing[4]

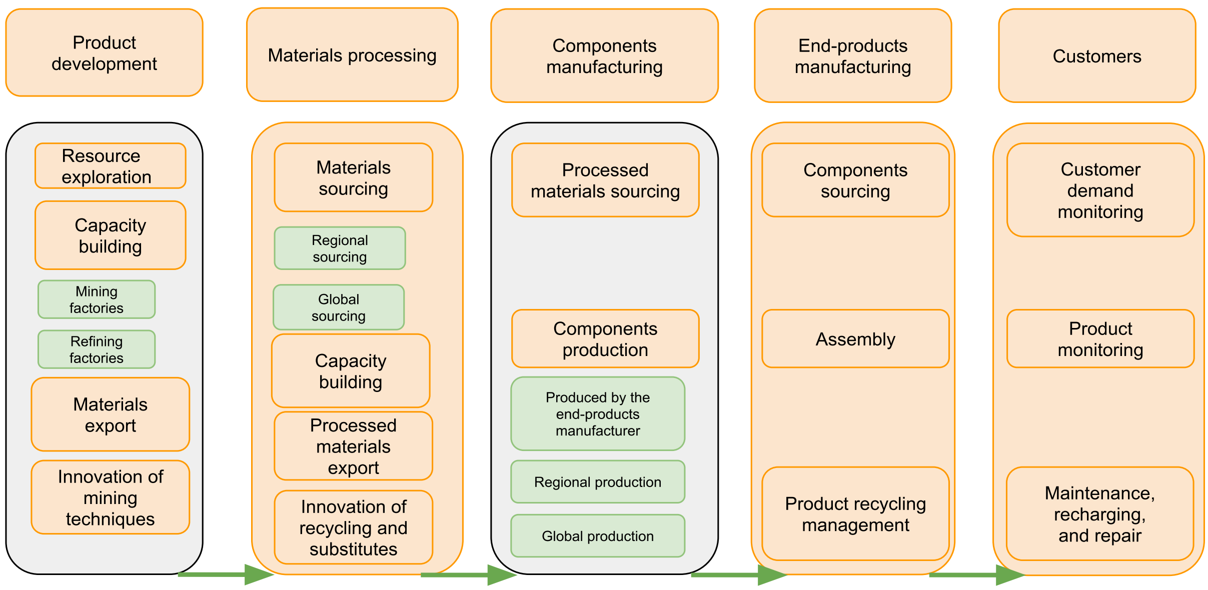
According to Raza (2021), the value chain of EU healthcare manufacturing includes R&D, components manufacturing, assembly, distribution, marketing and sales, after sales service. In this graph, the stages which CRMs can influence are R&D, components manufacturing and

[4] Raza, W. et.al. (2021) Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy.

assembly of end-products. At the R&D stage, there can be research on substitute materials as well as materials recycling mechanisms within the company. There could also be research on how to spare CRMs input per unit.

Then, it comes to the components manufacturing and assembly of end products. It should be noticed that the end-product manufacturers can either produce components by themselves or order components from component suppliers. It depends on the cost efficiency of producing a specific component.

Relatively high-value activities are increasingly located in pre-production (e.g., research and development, design), key components production process, and post-production services (e.g., brand, and finance) in value chains (Gereffi, 2020). If the first three stages can be largely controlled by the company, then it is possible to reduce transaction cost and the company can keep the know-how and value generation from key components manufacturing within the company as much as possible. However, the supplies of raw materials cannot be under the control of companies, as manufacturers are not miners and are not located to the resources. To create value from the CRMs, the tasks for managers to do is to figure out an efficient sourcing pattern (Matthias, 2013).



Graph 8: Value generation in the value chain of the healthcare industry with a focus on critical raw materials

If we focus on how critical raw materials are involved in the value chain of the EU's healthcare industry, it is obvious to see the critical raw materials' fundamental importance.

Depending on the sourcing pattern of the key components needed by the manufacturers, value erosion or value generation can happen at any stage in the value chain. To make decisions for the value chain, it is important to evaluate the capacity and probability of a sourcing pattern for the materials required.

In addition, there is a phenomenon of the constant preference of medical devices with high performance. It means, the value created from any improvement in the value chain will not be too difficult to acquire customers' recognition. Hinrichs-Krapels *et al.* (2022) analysed the customer's purchasing behaviour for high-cost medical devices including surgical robots, medical imaging equipment, defibrillators and orthopaedic implants. There is an expectation of returns in high-income settings by using high-cost medical equipment. However, the expectation from customers brings unavoidable dependencies on the critical materials to maintain the high performance, even if the medical companies may be put at a disadvantage getting access to these materials. The expectation pushes manufacturers to try to figure out value creation methods from the supply side.

3.Methodology

3.1. Case study

Case study research is 'an empirical inquiry that investigates a contemporary phenomenon within its real life context' (Yin, 1994). In this master's thesis, two methods of case study research will be applied, which are, multicase study and cross-case study.

Multicase study requires a selection of cases which have similarity in some ways (Stake, 2006). When the focus of the case study is a highly-concentrated phenomenon, cases should be special rather than a selection of all cases. The method is especially important, when the researcher aims to find out 'how the phenomenon performs in different environments' (Stake, 2006).As multicase research is based on individual cases, it is important to learn about individual cases' self-centering, complexity and situational uniqueness. It is the similarity and the uniqueness of individual cases that support a multicase study. Each sub-case with similar as well as unique characters is restricted by representation or relationship to the research program, but when they are designed together in a multicase study, the variables from each case can formulate the general picture. Based on these concerns, the selection of cases begins with cases which are partially identified. Then, suitable cases which are more representative and important for the topic will be selected out from the pool of candidate cases (Stake, 2006).

The rationale for a cross-case study is to understand both similarities and differences among many cases rather than only finding similarities among cases (Stake, 2006). Differences among cases imply that there are situational constraints and situated experience in a single case, which are important for researchers to understand the phenomenon in different circumstances. A variety of possible answers extend the perspective of understanding a question. For a cross-case study, a matrix for generating theme-based assertions help to visualise and merge the findings. In this way, a triangulation for a multicase study can be done with assurance of answers and reduced biases (Stake, 2006).

The multicase study in this master's thesis is bound together by the idea to study the importance and impact of critical raw materials on the manufacturing of healthcare devices. The application of CRMs is wide in the healthcare industry including those CRMs which can not be clearly traced nor explained how much of the materials is applied in the production. One reason for the hard explanation is the low transparency of healthcare devices supply chain. Another reason is that some manufacturing areas are not significant enough, or are hard to find typical local companies or multinationals with an EU origin. For the healthcare industry, even though CRMs play an important role for manufacturing, the supply chain of CRMs is only a part of the whole supply chain for a complicated machine. The demand for CRMs may also be irregular and hard to evaluate in a case.

This master’s thesis has chosen three high-tech healthcare devices manufacturing areas based on Table 3 (see Chapter 2.5). Relevant statements can be found in industrial research reports, CRMs research reports, articles and EU-level official documents.

The three medical devices manufacturing areas are magnetic resonance imaging devices (or MRI systems), YAG lasers and an EU CRM Strategic Project on lithium niobate cochlear implant devices. For each specific area, representative EU firms will be analysed. Each case study will contain analysis based on the five strategies supply chain management model and five-point value chain management model (see Chapter 3.2).

Multicase study is appropriate for the thesis. This master’s thesis is based on the five strategies supply chain management model and the five-points value chain architect model, however, each single case has its unique character and practical experience, which means, not every single case can match all the ten criteria in the two models. For this study, it is rather important to understand how the business is operated, how the value can be created, and what are the focuses for manufacturers to perform better in the context of increasing criticality of materials and worries for supply risks of CRMs.

There is a cross-case study following the multicase study. There will be a comparative analysis on multinationals with an EU origin and EU local firms. Then, there will be a comparative summary on the manufacturing of three medical devices and critical raw materials policy including the Critical Raw Materials Act.

The aim for the cross-case study is to find the connections between policy implementation, political ideation and industrial practices. The contingent emphasis of autonomy and less dependencies by both the EU government and the EU industry is not a coincidence. A cross-case study can visualise the picture of their common approaches to realise self-resilience and self-development. In addition, the unique approaches by the healthcare devices manufacturers can imply the healthcare industrial solutions to go innovatively and independently.

The first case study relates to magnetic resonance imaging devices. MRI imaging technology is a representative medical imaging technology. Diagnosis is an essential and indispensable part of medical service which requires input of diagnostic medical devices (Danti. *et al.*, 2023). In addition, MRI devices are also necessary for medical research and technology innovation. There's an increasing demand on diagnostic imaging devices offering exceptional image clarity, more accurate diagnoses and minimal radiation exposure (Statista, 2024b). At the same time, improved cost effectiveness and accelerated diagnosis speed are also important product attributes. Multinational healthcare devices manufacturers keep innovating their technologies and products to lead the market trend and exert an influence on customer preference. The diagnostic imaging devices market in Europe is anticipated to achieve US$16.25 billion by 2024 and US$20.12 billion by 2029. In comparison to less than €1 billion in the European market in 2011, it will be a substantial revenue growth in the future.

MRI devices manufacturing is an oligopoly in the global market and is mastered by a limited number of multinationals. Among the multinationals, the EU multinationals take the first and the third place: Siemens Healthineers (24%) and Philips Healthcare (20%) (Statista, 2024b). The cases are chosen for studying EU multinationals' activities in the healthcare industry. Different from local European medical devices manufacturers, multinationals have a relatively stronger global collaboration network because of their large partner landscape and their open visions on commercial opportunities.

As large international companies, Siemens Healthineers and Philips Healthcare are also important supporters to contribute to the EU's industrial autonomy, including in the healthcare sector. Their supply chain activities involve both REE and non-REE materials. Thus, it is important to understand multinationals' operational focuses on critical raw materials issues.

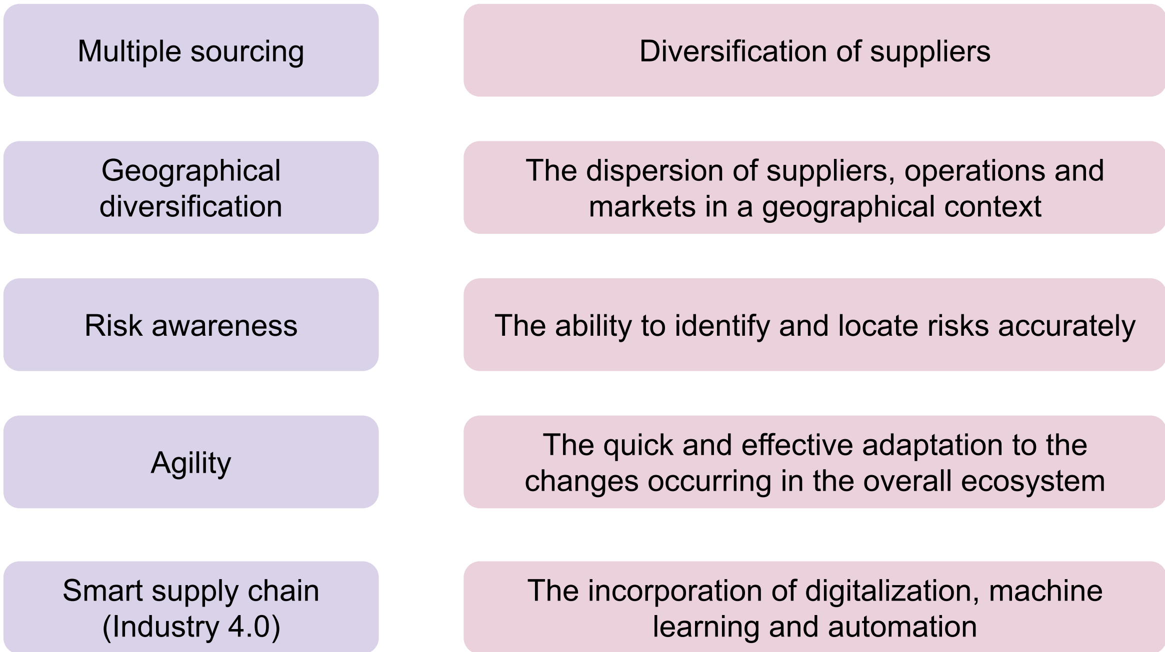
The second case study is the Nd:YAG lasers (neodymium-doped yttrium-aluminium-garnet lasers). Nd: YAG laser devices are used in many medical applications, e.g. endoscopy, dermatology, wound care, and many kinds of surgeries. where it produces a short-pulsed, high-energy light beam to cut, perforate or separate tissue (Annis, 2024). In other words, when the light is shed on the Nd:YAG crystals, the neodymium element will generate laser beams which are invisible to naked eyes but can go deep into the skin. Among all types of YAG lasers, Nd:YAG laser (neodymium-doped) does not harm skin epidermis and saves energy, thus it is the safest option and is most commonly preferred (Annis, 2024).

The Nd:YAG laser case is special because it involves two kinds of REEs, namely, yttrium and neodymium. It is hard to handle the supply side, when the world yttrium is solely sourced in China, and the neodymium raw materials and processed materials are mainly produced in China. The case provides a typical example of EU local firms confronted with challenges of REEs sourcing. We searched on a professional website for optical and imaging procurement 'Photonics Marketplace' and the result was not ideal. There were not many companies with a European origin for Nd:YAG lasers. We've found a European supplier with a wide range of optical products - Meetoptics. The newly-founded company is funded by the European Regional Development Fund to build a community for suppliers to deal with supply disruptions. Furthermore, we also used search engines to find European manufacturers for Yag laser machines like Zeiss and MTech Laser. For component manufacturers and medical device manufacturers, reducing dependencies on critical raw materials is not only a part of supply chain strategy, but also contributes to building core competence.

The third case study is cochlear implants (CI), recognised EU CRM Strategic Project which is an example of CRMs' innovation in medical devices (Danti. *et al.,* 2023). According to the World Health Organisation (2024), over 5% of the world population are suffering from disabling hearing loss, 20% of which is in developed countries. Even though the size and weight of Li-Nb cochlear implants is magnificent like MRI machines, cochlear implants are an important medical device which has sustainably increasing market opportunities in the European market. In this case, two non-REE materials (niobium and lithium) are discussed. The case can provide an understanding of openness by giving an example of high participation of third countries in the supply chain. The materials sourcing pattern and manufacturing pattern may raise thoughts about the extent of openness.

3.2. Theoretical models

3.2.1. Five strategies for healthcare supply chain resilience



Graph 9: An illustration of the Five Strategies for healthcare supply chain resilience

Five strategies model is a model for supply chain management which is used by Rehman and Ali (2021) to analyse the supply chain healthcare supply chain resilience. Five strategies refers to multiple sourcing, global diversification of suppliers, risk awareness, agility and smart supply chains (industry 4.0), The main concern of the theory is risk management and resilience to the occurring disruptions. The strategies are the solution to cover ten most significant risks in the supply chain. They are supply-demand mismatch, key supplier failure, sudden demand shocks, disruptions and delays in supply, quality risk, uncertainty in market, extreme weather, storage contamination risks, pandemics and epidemics, non-availability of materials. A resilient supply chain should be able to 'accurately predict, identify, locate, respond to and recover from the occurring disruptions' (Rehman and Ali, 2021).

Multiple sourcing refers to 'a resilience strategy where a supply chain diversifies its reliance on multiple suppliers'. The diversification of suppliers can assure the minimisation of the disruption risks brought by the failure of one supplier. Furthermore, an increased number of choices could add the buyers bargaining power. Generally speaking, the potential disadvantage for this strategy may exist, which is, multiple suppliers increase the probability of occurrence of risks. That's why an evaluation of the trustworthiness of each relationship is important to lower the probability of occurrence of risks. Whatsoever, in comparison to the risks brought by supply disruptions by a single supplier, multiple sourcing has great advantage in case of inevitable events. To some extent, increasing reliance on other suppliers may also reflect a decreasing reliance on the suppliers which are considered to have too much bargaining power.

Different from multiple suppliers strategy, geographical diversification which refers to 'the diversification of suppliers, operations and customers in a geographical context' (Rehman and Ali, 2021). It emphasises the suppliers' original region and home country. The geographical background of the supplier rather than the supplier's capability is evaluated, which implies an emphasis on the external factors rather than the internal factors. External factors can be political antagonism, trade friction, custom, export restriction, materials extraction restriction, environmental protection initiatives and so on.

Risk awareness refers to 'the supply chains' ability to predict, identify and locate risks in a timely fashion' (Rehman and Ali, 2021). Theoretically, in a supply system with information flow, materials suppliers, semi-products suppliers, manufacturers of finished products, distributors, all of the entities of the supply chain should have the ability to sense and recognise risks. Whether theoretical belief on dialogue and relying on coordination of supply chain risks with partners is dependent on efficiency concerns (Molthof and Köbben, 2022). Each supplier is an integral part of the supply chain and prevention of potential loss and creating competitive advantage of the supply chain is a mutual benefit (Nguyen et al., 2021, in Rehman and Ali, 2021). However, in the case of CRMs supply, generally the average mining and refinery capacity per year per mine is stable, the materials supplier is rather a challenger in the supply chain than a cooperator, when the selling behaviour is at the wish of materials suppliers. Sometimes, the manufacturers have to take the main task to monitor and sense risks and coordinate other entities in the supply chain. Thus, it is important for the manufacturers to coordinate as many entities as possible for the associated advantage.

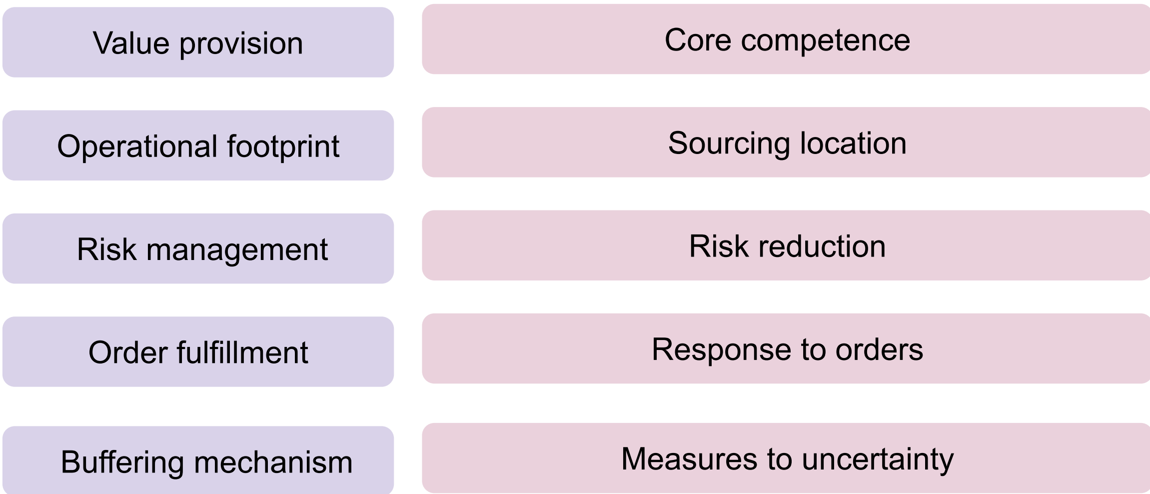
To manage agility in the healthcare supply chain means 'to serve as a coping mechanism in a turbulent or quickly changing ecosystem' (Agarwal *et al.,* 2007 in Rehman and Ali, 2021). It requires effective response to occurring changes in the supply chain with mitigation tactics. The capability of agility is dependent on many factors, the stock of the materials and semi-products needed, the financial situation such as cash flows, the experience of dealing with similar situations such as outbreak of diseases. In the case of a healthcare supply chain involving CRMs, the agility is also dependent on how medical device manufacturers compete for CRMs' resources such as alloys with other industries.

Smart supply chain emphasises 'a network of real-time data sharing and management of operations', which means to build business intelligence to serve the productivity, quality and efficiency management in supply chains (Pfohl *et al.*, 2015 in Rehman and Ali, 2021). However, real-time monitoring of risks needs high informative interaction in the supply chain. In addition, to avoid disruption through optimisation of inventory management and scheduling, a better understanding of customer needs such as their requirement of price, quality, delivery, maintenance and so on.

3.2.2. Five-point model of a value chain architecture

Holweg and Helo (2014) studied the case of electric machine manufacturing and designed a model to analyse the value chain management of large machinery manufacturing. The value chain architecture is not fixed. It is flexible and develops itself when the objectives and actions from the organisation evolves. A value chain architecture contains five domains: value provision, operations footprint, risk management, order fulfilment strategy and point of customisation, and buffering mechanism (Holweg and Helo, 2014).

Value provision relates to the core competence of the company, the question of which is to define which parts in the supply chain should be accomplished by the company itself and which parts are better to be outsourced. The reason for manufacturing by the company itself can be skillful workforce for manufacturing and assembling, higher control over precision on the assembly. As many medical devices are AI-controlled or computed, programming and testing creates a core competence in the manufacturing. This stage must be finished within the company. The reasons for outsourcing can be that the company acquires reliable and experienced suppliers. In the supply chain, each participant is expected to be skillful and specialise in their own business. Other concerns on outsourcing can be environmental protection or a favourable political environment.



Graph 10: An illustration of the Five-point model on value chain architecture

Value provision relates to the core competence of the company, the question of which is to define which parts in the supply chain should be accomplished by the company itself and which parts are better to be outsourced. The reason for manufacturing by the company itself can be skillful workforce for manufacturing and assembling, higher control over precision on the assembly. As many medical devices are AI-controlled or computed, programming and testing creates a core competence in the manufacturing. This stage must be finished within the company. The reasons for outsourcing can be that the company acquires reliable and experienced suppliers. In the supply chain, each participant is expected to be skillful and specialise in their own business. Other concerns on outsourcing can be environmental protection or a favourable political environment.

Operations footprint decides the concrete location of manufacturing and sourcing, which focuses on operational performance in response to global supply and demand changes. A key concern in this domain is the guarantee of key components' supply, whether it is from suppliers within the EU or from third-countries. In the sector of CRMs and healthcare devices, key components can not be substituted. It is important to guarantee the supply of critical raw materials for the key components and make sure that the materials are received by the key component producers at the right time. Cost efficiency is dependent on a suitable lead-time which takes the demand and the inventory of CRMs, the production capacity of CRMs suppliers and the price elasticity of CRMs into consideration.

Risk management refers to the mechanism which can be used to reduce risk exposure to production disruptions. The solution to the question requires the evaluation of the reliability of suppliers supplying certain materials or components for the decision making. The choice of local sourcing and global sourcing is dependent on the result of risk evaluation. Generally speaking, in the context of global trade, global sourcing has more uncertainty but also the benefit of cost efficiency. In the case of CRMs' supply chain to find an equilibrium between local sourcing and global sourcing, such issues are important for value creation: the management of inventories of primary resources, secondary resources and semi-products, the planning of lead-time in which the manufacturers can obtain resources for manufacturing at the right timing.

Order fulfilment strategies applied in manufacturing of electrical machines or heavy machinery are assembly-to-order and make-to-order. In the assembly-to-order mode, the manufacturer has stocks of components and can produce the final products within a limited time. The value is created from the time efficiency and amount of orders. In make-to-order mode, the manufacturer sells the products based on original design to meet the customer's order, there's no stocks of components, but the procedure from materials purchasing to final manufacturing are already specifically designed and can be reproduced once the order is received. The inventory level can be reduced to a minimum. The value is created from low inventory stock cost and specialised design.

Buffering mechanism relates to measures to deal with uncertainty, for example, supply unreliability and market unpredictability. A buffer can be any resource in the supply chain such as inventory of materials and stocks, production capacity and network structure, location and logistics or a combined management of all.

4. Analysis and findings

4.1. Case study

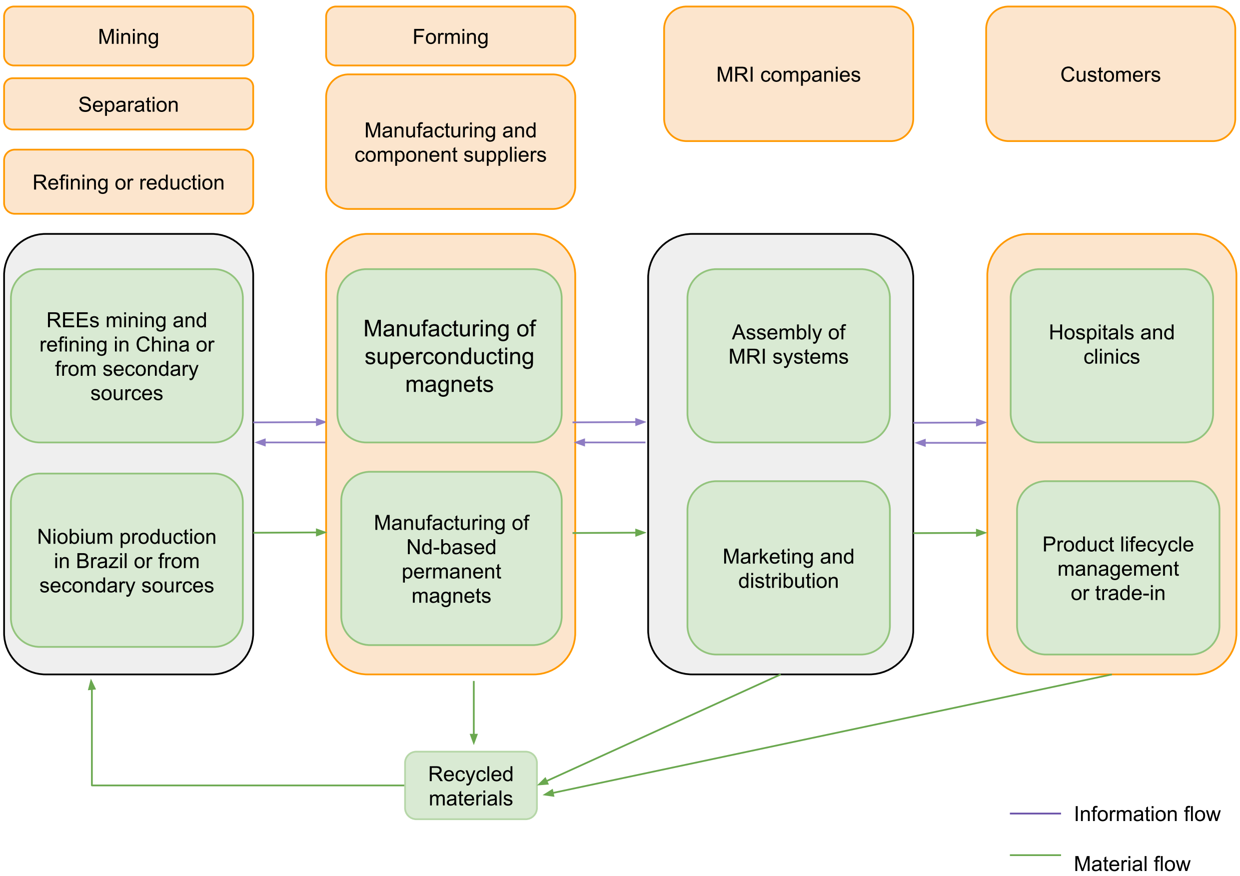
4.1.1. Magnetic resonance imaging devices

There are two types of magnets applied in MRI system manufacturing: superconducting magnets and rare-earth-based permanent magnets (Bacher, *et al.,* 2013). The difference between superconducting magnets and rare-earth-based permanent magnets determine that the European MRI system manufacturers produce its MRI system with both types of magnets (Nanalysis, 2020). Superconducting magnets are powerful and have the shortest scan time (Parizh *et al.,* 2017). But, they do need a strong cooling down system supported by liquid helium (Bacher, *et al.,* 2013). Till now, the price of liquid helium increases constantly, it can be very costly in the future (Bacher, *et al.,* 2013; Parizh, *et al.,* 2017). MRI systems with superconducting magnets can be expensive to produce, and they can be also expensive to operate because of the energy lost as heat in the windings (Nanalysis, 2020).

MRI systems with permanent electromagnets are easier to produce and the value is created through the reduced costs of producing other parts for an MRI system; moreover, MRI systems with permanent electromagnets are convenient to operate because of stability and permanent magnetic features (Nanalysis, 2020; Bacher, *et al.,* 2013). The permanent magnetic feature is rooted in rare-earth elements used in the magnets (CMS Magnetics, no date). Thus, till now MRI systems using REEs-based permanent magnets are more often used in medical apparatus manufacturing, for example, MRI machines and smaller machines like spectrometers (Nanalysis, 2020). That's why the European MRI system manufacturers have stocks of both types of magnets for their manufacturing to meet the customer preference (Bacher, *et al.*, 2013).

Supply chain

The Graph 11 shows the EU’s supply chain of MRI medical devices with a focus on critical raw materials. The supply chain of MRI system manufacturing begins with the mining of ores, separation and refining of raw materials. Speaking of niobium, the niobium production can come from primary and/or secondary sources and 82% of which is concentrated in Brazil, while 16% of which generate from Canada (SCRREEN, 2020a). The recycling of niobium is functional recycling which comes from secondary material (SCRREEN, 2020a). The application of processed niobium material is much more preferred than niobium from secondary material or product because of recycling reasons (SCRREEN, 2020a; Bartl, *et al.*, 2018). Speaking of neodymium, this rare earth element is widely used in non-superconducting electromagnets for MRI and other medical imaging devices. The mining and refining of neodymium is concentrated in China.



Graph 11: The EU's supply chain of MRI medical devices with a focus on a double-sourcing mechanism and product lifecycle management[5]

The second stage of the supply chain is the forming and components manufacturing which are located in Europe, North America and Asia. While large European companies like Siemens Healthineers and Philips Healthcare have the capability to produce superconducting magnets for their own MRI systems, while Asia and America dominate the manufacturing of neodymium-based (NdFeB) and gadolinium-based permanent magnets (Bacher, *et al.*, 2013;

[5] Source: Bacher, J., et al.(2013) Internal report summarising the results of ICT and electronics sector analysis.

SCRREEN, 2020b). There are European suppliers of NdFeB magnets, however, they buy refined neodymium from China (SCRREEN, 2020b).

The third stage of the supply chain is the manufacturing of MRI systems. The assembly of MRI systems by European multinational companies include products applying both superconducting magnets and permanent magnets (Bacher, *et al.*, 2013). Neither superconducting magnets nor permanent magnets can totally overwhelm the other. On the assembly, European multinationals combine the second and third stage for MRI systems by using their own superconducting magnets and outsource semi-finished or finished permanent magnets (Bacher, *et al.*, 2013).

The MRI manufacturers also take the tasks of marketing and distribution of their MRI systems to customers like hospitals, private clinics and ambulatory surgery centres. From component processing to manufacturing, marketing, distribution, customer service and after-sales, the supply chain is highly integrated and controlled by the MRI manufacturers, except mining and refining.

Multiple sourcing	Oligopoly (limited number of suppliers in certain regions in the country mentioned)
Geographical diversification	Niobium (non-REE) for superconductor magnets is sourced from Brazil and processed in Europe. Neodymium (REE) for permanent magnets is sourced and processed in China.
Risk awareness	Constant risk awareness according to the two different sourcing patterns of superconductor magnets and permanent magnets.
Agility	Manage to use less resources for stock tonnes of magnets per product. Capable to provide products with either superconductor magnets or permanent magnets. Closed loop of supply chain.
Industry 4.0	Digitalised product life-cycle management for demand analysis, product promotions and recycling planning. Customer-oriented integrated supply chain.

Graph 12: An illustration based on the Five Strategies regarding the EU's supply chain of the MRI medical devices in the EU

The high concentration of niobium and rare earths raw materials in a single third country restricts MRI system manufacturers' choices within a limited number of suppliers in the same country. Nowadays, mining of CRMs is an industry characterised by monopoly or oligopoly. The landscape of mining and refining business in Brazil and China has been already formed for many years, where newcomers are rare to see (Bacher, *et al.*, 2013). In Brazil, there are three mining and refining companies which supply niobium and niobium products for global manufacturers. Among all of them, CBMM Niobium in Brazil has about 80% of the global market share; the limited numbers of REEs miners in China are national-owned and national-proven after the market for REEs mining and export was regulated by the government in the mid-2010s.

Geographical diversification is an indispensable step for supply risk management. Even though it might not be easy to implement at the beginning, such efforts are necessary for freeing European manufacturers from buying resources from a single third country. Niobium from Canada is a good example for geographical diversification of CRMs sourcing based on the EU - Canada partnership on CRMs (SCREEEN, 2020a). The only question is that the ores in Brazil contain much more niobium than the ores in Canada. The higher quality grade of ores in Brazil implies, the mining and refining of niobium is more efficient in Brazil than in Canada (SCREEEN, 2020a). While the amount of Nb2O5 in ores in Brazil is from 3% to 12%, the amount of Nb2O5 in ores in Canada is from 0.59% to 1% (SCREEEN, 2020a). The possible impact of geographical diversification of CRMs sourcing in Canada can be: 1) increasing cost of mining and refining as well as increasing cost on waste management; 2) lowering price volatility because of new participants in global niobium supply chain; 3) gaining bargaining power on niobium import in the long-term as long as there won't be a boom demand of niobium in the future. However, there's no guarantee which impact weighs more.

In terms of geographical diversification of REEs’ sourcing, there are a limited number of candidates for Chinese miners and an increasing number of candidates for Chinese processors. At the forming and components manufacturing stage, there are more global suppliers producing NdFeB magnets. Finnish and German companies are also able to produce NdFeB permanent magnets for medical imaging devices (Bacher, *et al.*, 2013). There are REEs miners which are multinationals like Neo Company, the company has exploited its mining business of REEs in Europe and is establishing a permanent magnet supply chain to serve European industries, including medical imaging manufacturing (Neo, no date).

However, to what extent the company's mining capacity is able to fulfil the needs from the European manufacturers including medical devices manufacturers, the question is open. Even though now the Neo Company has production capacity in the EU, it doesn't mean that the miner no longer imports REEs from China.Such critical raw materials suppliers like Neo Company have two identities, one is miner and primary material processor, the other is importer.

Risk awareness should be raised at both the mining and component manufacturing stage. The situation is a bit different when it comes to niobium-based superconductors and REEs-based permanent magnets. The risks on the supply chain of MRI systems using REEs-based permanent magnets are relatively higher, when intermediaries on the supply chain increase and the manufacturer does not have direct contact with the miner/refiner. An increasing number of intermediaries might prolong the lead time, because of additional communication and negotiation and the current stocks by the miners, the component manufacturers and the MRI systems manufacturer itself.

To enhance agility, more concrete time management to guarantee supply is necessary to respond to customer's demand. On one hand, MRI devices are big, heavy, and the inventory of a large amount of end-product is not efficient. On the other hand, MRI systems manufacturers are establishing a tighter communication mechanism through digitalisation with hospitals, so that the manufacturers can interpret customers' need for replacement of devices, components, sale-back as well as emergent breakdown.

Value chain

Value chain improvement aims to serve the affordability and accessibility of diagnostic imaging devices (Statista, 2024b). It is also a long-term trend in the MRI systems market. Value creation at the manufacturing stage is guaranteed by continuous technological innovation in niobium-containing superconductors and assembly and refurbishment of end-products. To guarantee efficiency and enhance product competency in the context of possibly increasing supply risks in the future, MRI systems manufacturers tend to develop products using critical raw materials with less supply risks and better prospect of recycling. An important difference between the acquisition of niobium from Brazil and neodymium from China is that Brazil dominates only the mining and refining stage, while China dominates the mining and refining stage and performs a leading role in the permanent magnets market. A trend for MRI magnets in Europe will be an increasing application of niobium-based superconductors, which is expected to free MRI system manufacturers from REE-based magnets which can finally contribute to the EU's healthcare autonomy. In fact, in 2024, Siemens made a breakthrough on the superconducting magnets MRI system with much lower input of helium for cooling for manufacturing and lower energy cost (Ridley, 2024).

Value provision	All factors which contribute to improving performance as well as affordability and accessibility of diagnostic imaging devices. Costly MRI with superconducting magnets for high-end customers; MRI machines with permanent magnets for rural customers and customers with limited budgets.
Operational footprint	Increase in-house material processing of CRMs with relatively less supply risks and better prospect of recycling.
Risk management	All-dimensional technological development for non-REE materials to substitute REE materials.
Order fulfillment	Assembly-to-order.
Buffering mechanism	Innovation and research on saving energy costs and manufacturing costs for superconducting magnets; Product life-cycle management; Cooperative value creation: recharge of magnets; trade-in/buyback values; Input of AI technology to support magnetic performance.

Graph 13: An illustration based on the Five-points model regarding the EU's value chain of MRI medical devices with critical raw materials

Considering the situation, the recycling of niobium is an increasingly important topic. Currently, the level of recycling of niobium is about 1% and it is scraped from niobium-containing steel and used in steels. (SCRREEN, 2020a). In comparison to steels, MRI scanners are niobium-rich products Even after the life-time of the superconductors, the contained niobium elements can be remanufactured as a reliable waste stream (Beta Technology, 2024).

Speaking of recycling and reshoring of critical raw materials, in the future, a contribution to the value chain could be made to the recycling potential of MRI magnets. Apart from niobium-containing superconductors recycling, the recycling techniques of REEs-doped permanent magnets is also developing. An American company Noveon has found a method to recover neodymium-doped magnets and can save 90% energy cost, which could be viewed as a start of applicable REEs-based magnets recycling or scraping. As permanent magnets including MRI magnets are the main secondary materials for the recovery of neodymium and gadolinium, the recycling of MRI magnets is important because in this way the REEs resources can be fully exploited in Europe and the worries on supply risks can be relieved. It implies that the value of materials can be absorbed in the supply chain of MRI systems and generate more value for the supply chain. The SCRREEN research project, funded by European Union's Horizon 2020 research and innovation programme, has proposed manganese as a substitute used in permanent magnets for MRI systems and viewed the performance similar with the support of enhanced computer technology and artificial intelligence. Manganese is not a critical raw material and is not confronted with high supply risks.

The order fulfilment model of MRI systems manufacturing is assembly-to-order (ATO). The MRI system is a service mix of the medical device - MRI scanner and the AI-supported computing system. The manufacturers offer a series of products based on their materials input, inserted computing system and after-sale service. Moreover, for innovative high-tech industries, the more stages of the supply chain the manufacturer can control, the more things the manufacturer can do to optimise the efficiency of materials used, for example, research and development on superconductors-related technology and energy saving systems.

The buffering mechanisms for MRI systems manufacturing will show more flexibility to create more value. Rather than purchasing more raw materials to fulfil the inventories, MRI manufacturers tend to prolong the life cycle of MRI magnets. They are encouraging customers like hospitals to work together on product life cycle management. The idea focuses on sustainable exploitation of available materials and scientific innovation in Europe.

Siemens Healthineers has launched a systematic program - asset lifecycle development (Siemens Healthineers, no date (a)). The program aims to continually extend the life span of medical imaging systems and contribute to a circular economy within the boundary of the company's business. On one hand, the system makes it possible for the company to buy back used medical equipment and medical imaging systems (Siemens Healthineers, no date (b)). The company can exploit left values in pre-owned products or components and create new values through recycling and reproducing. It helps the company to save materials input. On the other hand, as this system involves and encourages customers to plan ahead together with Siemens Healthineers on a sequence of issues, for example, timing of the purchasing, replacement and upgrading of the equipment or component (Siemens Healthineers, no date (a)). Furthermore, the system makes a closed loop for products and materials, which means, the purchasing and recycling are operated by Siemens Healthineers, there is only one way in and one way out, which implies the company's control over supply chain and value chain (Siemens Healthineers, no date (b)).

Philips Healthcare has a similar system named SmartPath for MRI systems which focuses on continuous technology upgrade and lifetime extension (Philips Healthcare, no date). SmartPath is supported by dStream technology developed by the company which aims to prolong the lifetime of magnets through upgrading digital computing capability which helps to provide more precise 2D and 3D images (Philips Healthcare, no date).

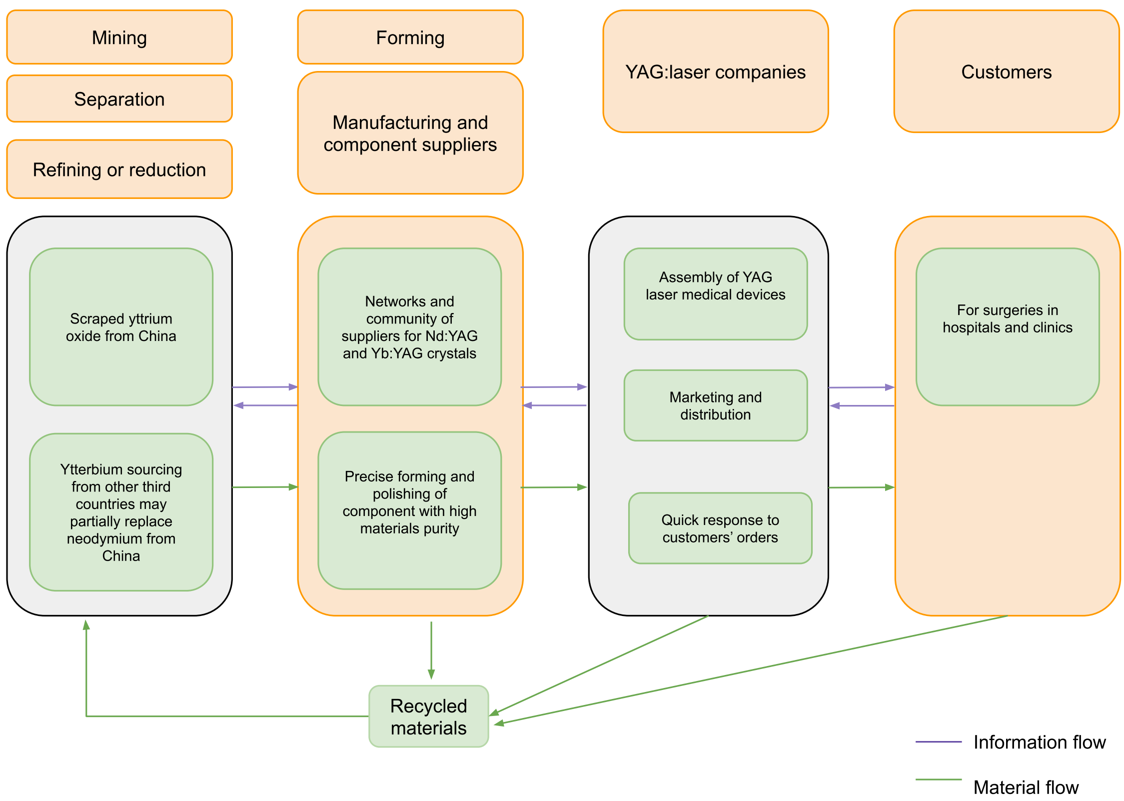
The timing for the company to prepare materials for manufacturing and remanufacturing is largely dependent on the customers' requests. When this double-directional information flow is well-organised, the digitalised systematic after-sales system can be a guide for the company to plan and predict the timing for dismantling, adding orders of raw materials and components and recycled materials on the supply chain.

4.1.2. Nd:Yag-laser medical devices

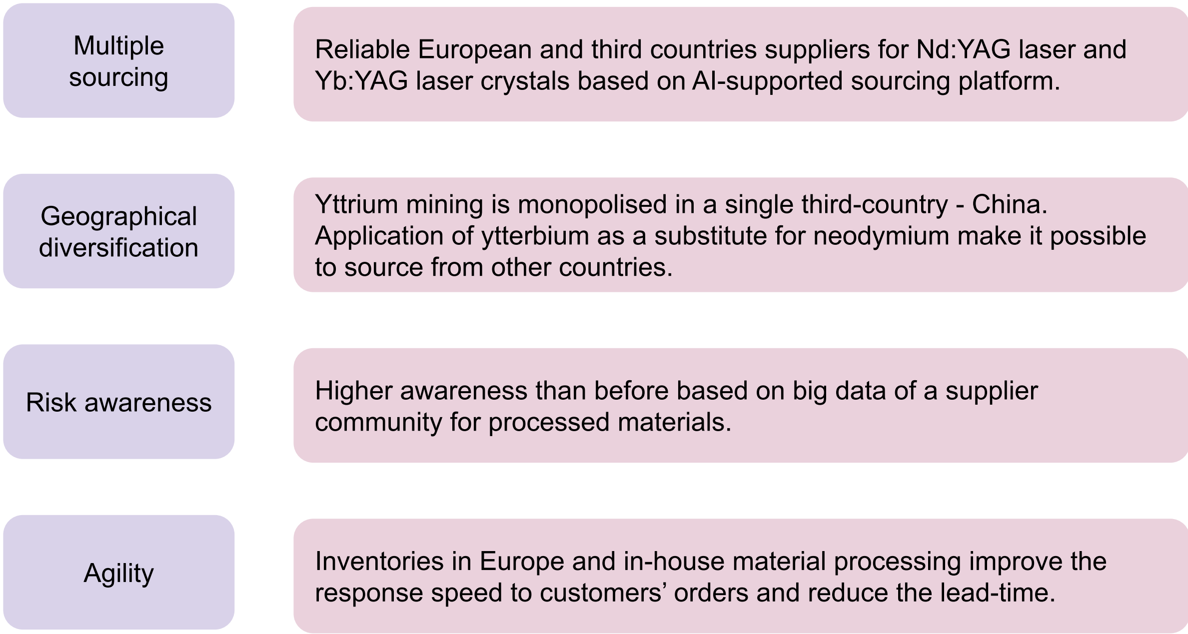
The manufacturing of the Nd:YAG laser components requires rare earths neodymium and yttrium. The European manufacturers import processed material - Nd:YAG crystals - from China. As neodymium is tarnished very fast in the air, it requires strict storage and processing techniques to guarantee the quality before it is further processed (Palomar, 2016). And this is a reason for the higher monopoly of neodymium's supply by China. In comparison to other rare earths, the geographic monopoly of neodymium is relatively high. After the import, the crystals will be further manufactured into optical key components and delivered to manufacturers for the production of diode laser devices. These devices are utilised for eye surgery, beauty therapy, skin cancer therapy and so on.

Supply chain

For component manufacturers and medical device manufacturers, reducing dependencies on critical raw materials is not only a part of supply chain strategy, but also contributes to building core competence. In the European market of Yag laser components and Yag laser devices, there are more participants. For example, in laser treatment for beauty and skin, there're not only European companies but also international companies from third countries which have established their European headquarters, e.g. Lutronic from South Korea. To compete with competitors from third countries in the European market, it is important for local manufacturers to strengthen the supply chain of raw materials, polish manufacturing skills and push forward technological innovation.



Graph 14: The EU's supply chain of Nd:Yag lasers with a focus on sourcing access and capacity building



Graph 15: An illustration based on the Five Strategies regarding the EU's supply chain of Nd:Yag lasers with critical raw materials

To deal with supply risks as well as to gather trusted suppliers for processed materials and components, the company Meetoptics was established in 2019 in Spain. The platform is financially supported by the Spanish government and co-financed by the European Regional Development Fund from 2019. Meetoptics aims to build 'a global optics and photonics community' with a high variety of optical components for EU manufacturers (Meetoptics, no date (a)). There are various crystals with YAG laser with different sizes and forms in stock from a limited number of reliable suppliers, including EU suppliers and suppliers from third countries (Meetoptics, no date (b)). If the processed materials are not in stock, it takes 4 to 8 weeks to deliver the materials. Inventory management is an important business for Meetoptics. The company functions not only as an AI-facilitated platform, but also as an inventory manager for fast delivery of thousands of optical processed materials and components. In the example of Meetoptics, supply risk management is supported by digitised networks and big data as well as by constant inventories at the stage of component sourcing.

Apart from the traditional Nd:Yag laser, there is a potential substitute Yb:YAG laser (ytterbium-doped yttrium aluminium garnet) which has excellent thermal and optical properties (Samaterials, no date). In medicine, Yb:YAG material enables 'precise surgical procedures, dermatological treatments, and dental surgeries with minimal thermal damage' (Samaterials, no date).

The existence of substitute materials may bring changes to current geographical sourcing patterns. There are more flexible sourcing ways of ytterbium than neodymium elements. And the EU component manufacturers can dope ytterbium and neodymium in the YAG crystals. For instance, it will be possible for European component manufacturers to source ytterbium from discarded sections of defective boules from crystal warehouses in China, like what an American company Djeva has done with sourcing. Another possibility is to source from other third countries. According to Minor Metals Trade Association (2023), the ores required for ytterbium can also be acquired in the USA, Brazil, India, Sri Lanka and Australia. In addition, neodymium is much more difficult and costly to extract and process and to guarantee purity. Actually, Meetoptics already has Yb:YAG crystals in stock, together with Nd:YAG crystals, for medical use. In-house stock and contact with suppliers can greatly improve the response speed to customers' orders and reduce the lead-time (Meetoptics, no date (b)).

Value chain

The innovation of the material is gradually advancing the European suppliers from the stage of final products manufacturing to the stage of material processing and key component manufacturing. The European YAG lasers market is witnessing the change of the market share of different types of YAG lasers. The value creation based on the changes on the supply chain is accumulating in Europe with the development at the material processing stage. The change of sourcing location shows another way to deal with being trapped by unchangeable key components. When the material used for the key component is changed, the sourcing location can be changed subsequently, or the restriction for discarded stones is not so tight for ordinary mines. Moreover, the difference of processing techniques can also bring favourable changes to cost problems. Less difficult processing techniques for ytterbium than neodymium and less oxidation can contribute to cost efficiency.

Value provision	Depending on the types of Yag lasers, the stage can move from manufacturing to materials processing in the EU.
Operational footprint	Component suppliers in a supplier community. In-house end-products manufacturing.
Risk management	Global sourcing of substitute materials can change the sourcing countries. A worldwide supplier community based on AI and big data.
Order fulfillment	Make-to-order
Buffering mechanism	Technological innovation. Treatment performance enhancement of YAG with other metals. Efficient materials' input. Precise manufacturing technique.

Graph 16: An illustration based on the Five-points model regarding the EU's supply chain of Nd:Yag lasers with critical raw materials

Speaking of buffering mechanism, according to Zeiss, an Austrian therapeutic lasers' manufacturer, the manufacturing strategy should put emphasis on accurate manufacturing technique, which can guarantee precision and safety by treatment, prolong the life time of materials and reduce unnecessary wastage (Zeiss, no date). Another example for value creation is MTech Laser's three-waves laser technology (MTech Laser, no date). To improve the efficiency of application of YAG material, the company developed new technology to enhance the overall performance of the device. In this technological innovation, YAG material is combined with other two metals to achieve better performance. In this case, the potential of YAG material can be maximised within a limited amount of input.

4.1.3. The European Strategic Project in medical devices - lithium niobate cochlear implants

The cochlear implant is a multi-component electronic device made of 'electrospun fibres' which has good biocompatibility and flexibility (Candito. *et al*., 2022). Lithium niobate has particular properties such as superconductivity, biocompatibility and exceptional resistance

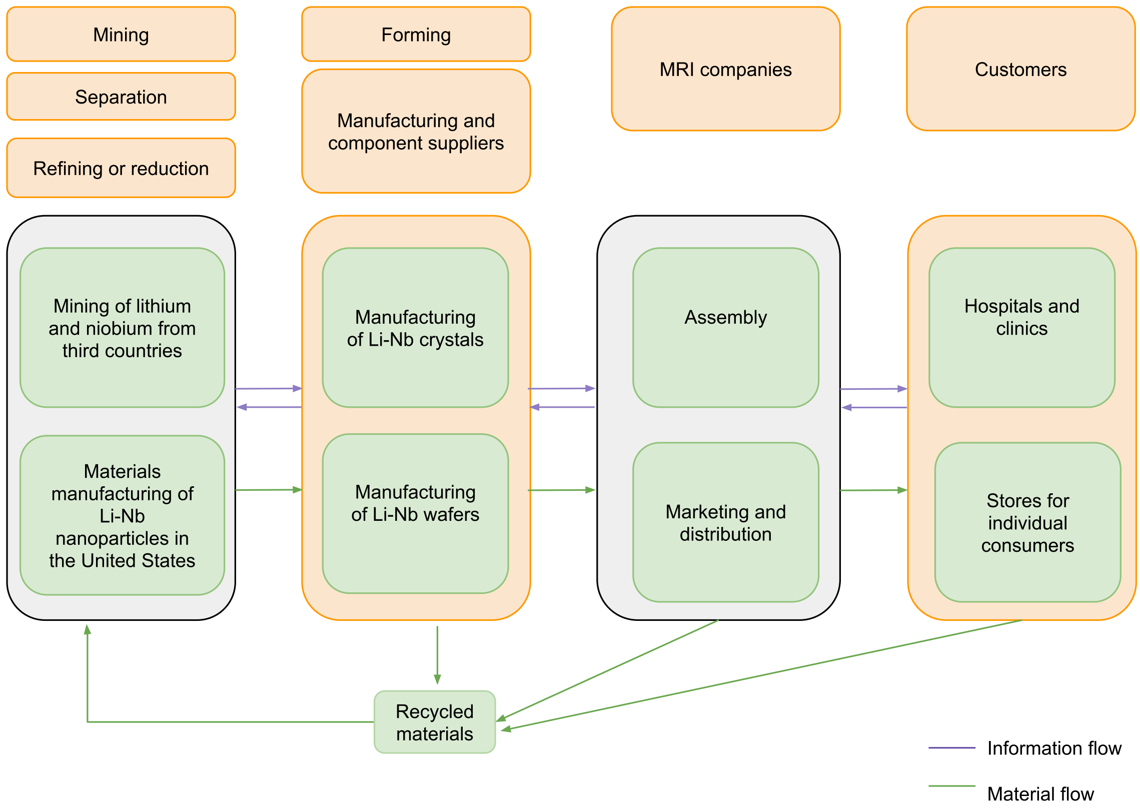
(Danti. *et al.*, 2023). Because of its particular properties, lithium niobate has a variety of industrial applications, such as optical waveguides, piezoelectric sensors, mobile phones and so on. In the case of cochlear implants, it is used as piezoelectric sensors. The introduction of lithium niobate can contribute to the performance of the cochlear implant device serving as a self-powered auditory stimulation (Candito. *et al*., 2022, Danti. *et al.*, 2020).

Same to many medical products, the traditional cochlear implants have side effects, which result from medical side effects or device failure. The addition of lithium niobate can decrease the side effect caused by mechanical-electrical energy transformation in the CI device, so that the cochlear implants device largely reduces damage to neurons (Candito. *et al*., 2022). Candito. *et al.*(2022) also studied barium titanate as a substitute which can also decrease the side effect, however, lithium-niobate has better compatibility to the nanoparticles on the neuronal cell line. In addition, the application of lithium niobate is also much more economical than substitute materials barium titanate (Candito. *et al*., 2022). In the case of Li-Nb cochlear implant devices, a change of materials is limited.

Supply chain

The sourcing design of this strategic project is based on the principle of the diversification of global partnerships, where sourcing from liked-minded countries and friendly-shoring is widely applied. In terms of mining, niobium is sourced from Brazil and Chile and lithium is sourced from Australia and Argentina; the processing of niobium and lithium into lithium-niobate crystals and wafers is finished in the United States; the manufacturing of the end-product is located in the EU (Danti. *et al.*, 2020).

In fact, 78% of the EU's total sourcing of lithium is from Chile and 8% is from the United States; 85% of the EU sourcing of niobium is from Brazil and 13% is from Canada. In comparison to the world's sourcing pattern of lithium and niobium, the EU does not source lithium from China, where the lithium reserves are supposed to fulfil the demand of China's own industrial manufacturing as a priority.



Graph 17: The EU's supply chain of lithium niobate cochlear implants with a focus on sourcing pattern and key component manufacturing

Multiple sourcing	No emphasis on multiple sourcing of lithium and niobium. High concentration of material processors in a single country (USA).
Geographical diversification	Separated sourcing of lithium and niobium. Friendly-shoring and sourcing from like-minded countries.
Risk awareness	Low awareness. Responsibility transferred to USA materials processors.
Agility	Cloud-based data system. Quarterly customer demand-tracking.

Graph 18: An illustration based on Five Strategies regarding the EU's supply chain of lithium niobate cochlear implants with critical raw materials

In terms of multiple sourcing, the EU project of cochlear implants devices does not emphasise the diversification of suppliers for the same resource in the same country, but diversification of suppliers for different resources in different countries. Geographical diversification weighs more than multiple suppliers.

If we only look into the materials required for Li-Nb cochlear implants, it is sufficient for the EU to produce based on its own import. However, the EU strategic project chose to put materials' processing and key component's manufacturing in the USA (Danti. *et al.*, 2020). . The concentration of manufacturing of Li-Nb material for Li-Nb components in the United States implies a phenomenon that there is a high geographical concentration of a single product's processed materials and key components in a limited number of like-minded countries. The suppliers of lithium-niobate in the United States manage the sourcing channel of raw materials from Chile, Brazil, Canada as well as from its own, in which the European cochlear implant manufacturers cannot intervene nor have an impact on the mining and extraction side (Danti. *et al.*, 2020).

What's more, in the case of high-tech medical products, responsible sourcing and transaction costs are more important criteria for the consideration of supply chain planning (Danti. *et al.*, 2020). The quality of the product directly impacts the life quality of the end-users, for example, the high requirement of a purity level of 99.9%. Thus, there is a preference for suppliers with a steady knowledge background and accumulated industrial experience, rather than suppliers from platforms like Alibaba and MSE Pro with more favourable prices but from other third countries. Furthermore, by sourcing from the United States, the cost of coordinating raw materials' suppliers from different countries is avoided; the time and the cost of training EU workers to produce Li-Nb key components is also avoided.

Agility of the supply chain of cochlear implants devices is based on data. For example, a cloud-based data system can track the hospitals' stock shortages, which are the largest market for cochlear implants devices. Data tracking can help manufacturers understand the demand and estimate quarter by quarter, so that manufacturers can make orders to the materials' suppliers (Sier, 2022). The current agility management, on one side, behaves actively when it comes to the customers, but on the other side, it behaves passively when it goes on with the suppliers. The problem is that it cannot help manufacturers to enhance its risk management capability when widespread shutdown, rising inflation and interest rates across the supply chain happens (Sier, 2022).

Value chain

Value provision	Key component sourced outside the EU, but in a like-minded country. Value created by price-quality efficiency on materials sourcing. Relatively lower price sensitivity.
Operational footprint	Sourcing origins and component quality dependent on USA material processors.
Risk management	High dependency on reliable partners.
Order fulfillment	Assembly-to-order.
Buffering machanism	Life-time purchases, inventories management,

Graph 19: An illustration based on Five-points model regarding the EU's value chain of lithium niobate cochlear implants with critical raw materials

The main value chain actors are miner and refiner, materials' manufacturer and key component's manufacturer and end-product's manufacturer (Danti. *et al.*, 2020). These actors' behaviours and their connections decide the question to what extent value can be created.

The core competence of the innovative cochlear implant device is contributed by the application of lithium niobate material which creates 'value efficiency by converting vibrations to electrical signals' (Danti. *et al.*, 2020). According to the five-point model theory, it is important to decide the production place of product parts across the supply chain. In the supply chain of new cochlear implants devices, lithium niobate is regarded as a key component because of its innovative meaning to the final product, however, it is outsourced from the United States. The choice of choosing US suppliers for key components can be the US suppliers channel to raw materials and processed materials - lithium niobate nanoparticles. Other important reasons are the manufacturing capacity for lithium niobate in the US, transaction costs for the EU, etc.

As mentioned above, lithium niobate in this case is hard to replace (Candito. *et al*., 2022). Sourcing of key components from like-minded countries is thought to be more reliable when it comes to supply risks, when there is an intermediary for the EU project to respond to supply risks. In this sourcing pattern, no country is able to supply both lithium and niobate raw materials. If the EU planner in charge of this project chooses to outsource the lithium niobate nanoparticles, efficient value creation should be to combine raw materials processing and key component processing in a single supplier to simplify the supply chain, considering the quality guarantee, time input and cost efficiency factors.

The volume of gross and net profit is rooted in the ability of revenue generation. In the period of Covid-19 pandemics, the revenue slid due to supply disruptions, slow response to customers' demand, bans and time delay on logistics across the supply chain (Sier, 2022). Lower revenues during the pandemics decreased the profitability of the business and eroded the value chain. Moreover, the world's widespread pandemics is a series of waves because of evolved viruses from delta to omicron, which means, the supply shortages were consequently confronted with a series of waves and that was the reason for a hard recovery from the impact of pandemics. In this circumstance, risk management across the supply chain is more than general tracking in peaceful times. The tracking system should be a construct based on the specific situation of the country where the CRMs are sourced.

The buffering mechanism should back up inventories to buffer any shortages, including end-products and components (Sier, 2022). As the contact to raw materials suppliers is mastered by the American lithium niobate nanoparticle suppliers, the buffering effect is dependent on the EU final product manufacturer's connection to the American suppliers concerning the Li-Nb material and the manufacturing capability to satisfy the stock of final products. To resist potential supply shortages of components which might stop producing in the short term, the purchasing of processed materials is a series of 'life-time purchases' (Sier, 2022). The planning for 'life-time purchases' needs the ability to predict market changes based on the observation on the amount of mining production, the demand increase and the price volatility.

4.2. Comparative analysis

The EU healthcare industry manufactures a large amount of medical products using critical raw materials which are hard to replace. The impact of CRMs policy of the healthcare industry directly reflects on medical devices manufacturing. The focus and change in their supply chain and value chain demonstrates the EU healthcare industry's as well as companies' pursuit for their own strategic autonomy in the great context of the EU industrial strategic autonomy and the legislation of the EU Critical Raw Materials Act. Political determination strengthens the standpoint of healthcare industrial endeavours to promote innovation in the supply chain.

Strategy for materials' sourcing is an integrated part of the supply chain ecosystem. It can influence the other parts and be influenced by other parts in the supply chain ecosystem. Strategic change aims to create more value in a relatively stable and trustful way in the long-run. There are a variety of factors which might influence change in the supply chain. It depends on the type of the product, the kind of customer needs, the access to new sourcing channels and so on. Among the factors, access to new sourcing channels can not only be explored by companies, but also deeply impacted by policy. The impact by policy is dependent on the extent of the policy's empowerment, comprehensiveness and relevancy.

The findings in this master's thesis indicate similarities as well as differences among multinationals with an European origin and the EU local companies (including EU strategic projects), when it comes to sourcing of REEs and non-REEs materials. It is because of the difference in manufacturing volume, the demand on a specific material, the application of substitute and potential of recycling as well as the difference in companies' perceptions and visions of globalisation and openness.

Content	MRI systems	YAG:laser	Cochlear implant
Multiple sourcing	Oligopoly (limited number of suppliers in certain regions in the country mentioned)	Sourcing for processed materials within and outside of Europe.	No emphasis on multiple sourcing. High concentration of material processors in a single country
Geographical diversification	Niobium (non-REE) for superconductor magnets is sourced from Brazil and processed in Europe. Neodymium (REE) for permanent magnets is sourced and processed in China.	Yttrium was restricted to a single third-country. New substitutes make it possible to source substitutes from other countries.	Separated sourcing of two raw materials. Friendly-shoring and sourcing from like-minded countries.

Risk awareness	Constant risk awareness according to the two different sourcing patterns of superconductor magnets and permanent magnets.	Higher awareness than before based on big data of a supplier community for processed materials and components.	Low awareness: awareness transferred to USA materials processors.
Agility	Manage to produce or stock tonnes of magnets per product. Interpretation and data analysis of customer demands.	Relatively lower risk than before, if more substitutes are proved to be applicable.	Cloud-based data system. Quarterly demand-tracking
Industry 4.0	Customer-oriented product life-cycle management for demand analysis. Integrated supply chain	-	-

Table 5: An comparative analysis of the EU's supply chain of MRI medical devices, YAG:lasers and lithium niobate cochlear implants

In respect of supply chain strategy, three models are displayed in relation to three sub-areas of medical devices manufacturing. The first model is complementary supply chains of different CRMs to support end-products manufacturing. The model is specialised for multinationals which have advantages on product innovation and supply chain integration. In this case, the substitute of a REE is a non-REE. Since both have advantages and disadvantages, none of the material can totally substitute the other. But still, multinationals are pushed to develop technology using CRMs with relatively less criticality, safer access as well as better recycling prospects, so that the pressure from the materials supply side will be eased.

The highlight of the second model is the access to a community of reliable suppliers based on big data and constant inventories in Europe. Another highlight is the realisable sourcing possibilities, which are secondary raw materials from the country of origin (China) and sourcing of substitute raw materials from other third countries. possibility of sourcing raw materials waste management (the import of secondary raw materials). The import of secondary raw materials can have less regulation risks. The change of the material can bring an opportunity. Even though the substitute for a REE is still a REE, the change brings a possibility for geographical diversification because the ores needed for extraction are different. As there are also materials' processors in Europe, access to new channels will encourage their manufacturing activities, which will be a business practice contributing to industrial autonomy.

The third model is designed to pass down the risks to trustful third-country suppliers which produce CRM-based components. In this way, the risks the EU manufacturer takes equals the risks that the American supplier takes. The idea is used by the EU strategic project on the innovative lithium-niobate cochlear device. The idea is also based on diversification of risks and easiness of supply chain operation, when suppliers for different CRMs and materials processors are totally from different countries. The necessary condition for this idea is that the key component producer is from a trustworthy third-country like the USA, that the supplier has the ability to manage the supply of raw materials and the know-how to guarantee the quality of key components.

All three models choose to locate at least the end-products manufacturing in the EU. It can not be helped that the mining and extraction of many CRMs still relies on third-countries. However, increasing diversification of global partners is dealing with the dependency problem. Furthermore, there is a tendency for the EU healthcare devices manufacturers to increase the share of key components manufacturing in the EU and decrease the share of key components manufacturing in third countries. The tendency demands the support from technology of substitute materials and support facilities for application of substitute materials, sourcing channels for substitute materials, materials recycling and waste management. All these factors will be improved in the future. In addition, products with relatively complex manufacturing processes, heavy weight of CRMs required in a single product and large product size should better be produced in the EU.

Content	MRI systems	YAG:laser	Cochlear device
Value provision	All factors which contribute to improving performance as well as affordability and accessibility of diagnostic imaging devices.	Depending on the types of Yag lasers, the stage can move from manufacturing to materials processing in the EU.	Key components sourced outside the EU, but in a like-minded country. Value on price-quality efficiency on materials sourcing. Relatively lower price sensitivity for sourcing.
Operational footprint	Increase in-house material processing of CRMs with relatively	Component suppliers in a supplier community including suppliers from	Sourcing origins and quality decided by USA material processors.

	less supply risks and better prospect of recycling.	the EU and third countries. In-house end-products manufacturing.	
Risk management	All-dimensional technological development for non-REE materials to substitute REE materials.	Global sourcing with increasing channels supported by big data and policy instruments.	Reliable sourcing. No economical substitute for lithium niobate.
Order fulfilment	Make-to-order	Make-to-order	Assembly-to-order
Buffering mechanism	Product life-cycle management. Upgrade of AI technology Inventory management	Technological innovation on substitutes and treatment performance. Efficient manufacturing strategy.	Inventories back-up for components and end-products. Life-time purchases of processed materials.

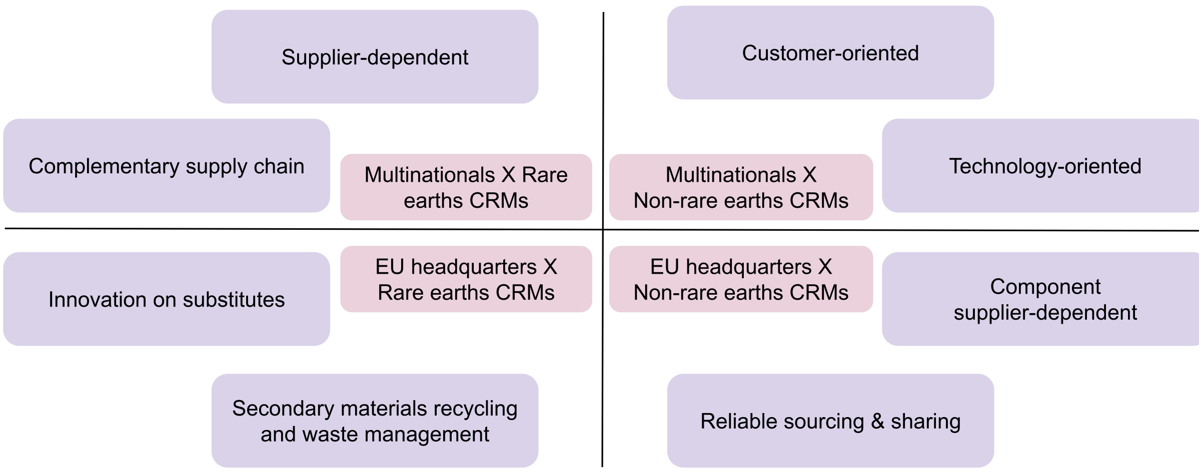
Table 6: An comparative analysis of the EU's value chain of MRI medical devices, YAG:lasers and lithium niobate cochlear implants

Optimisation of the value chain requires lower cost, higher added-value, less waste of time and materials, better information flow and so on. There is a rising demand for CRMs not only in the EU but also worldwide. The price of CRMs go upwards and the competition for CRMs in the world will also increase. The changes on the CRMs in the supply chain can be a crux for value creation.

With further developed global partnerships on CRMs issues and increasing capability of local CRMs supply, healthcare devices manufacturers will gain more flexibility to choose suppliers for raw materials or components. The change will bring affordable and accessible supply for CRMs and CRMs products. For example, healthcare devices manufacturers who only had access to component suppliers in the past can have access to the primary and secondary materials or recycled materials thanks to mining and processing of CRMs in the EU as well as innovation on recycling and substitutes.

In the EU healthcare industry, the supply chain is highly customer-oriented. The degree of impact of supply disruption is related to the volume of customer demand. To create value in an efficient way, it is important for manufacturers to keep a dynamic equilibrium of inventories and new purchases, so that cost for stocks can be reduced and the harm of a lasting supply shortage can be minimised. Product life cycle management by Siemens Healthineers, SmartPath by Philips, quarterly demand tracking by the EU CRMs Project lithium niobate cochlear devices improve analysis and prediction of customers' demand.

However, healthcare devices manufacturers do not have direct access to ores and extracted materials. Large multinationals can have access to primarily processed materials, when they manufacture further-processed materials on their own. It implies that ability to identify and locate risks accurately is restricted within the supply chain stages which is reachable for manufacturers. In this situation, quick and effective adaptation to changes is also limited within a certain range. The limitation suggests that there is still space for policy performance which can benefit healthcare devices manufacturers in the future.



Graph 20: Characteristics of the reactions in the EU's healthcare industry to the critical raw materials issues

A further discussion of the cases concerns the efforts that multinational and non-multinational EU healthcare devices manufacturers make on CRM-related issues. Their positioning on the supply chain, focus and solution to CRM-related issues vary, when it comes to rare-earths and non-rare earth CRMs. EU-based multinationals show more experience on international business than the EU companies which focus mainly or only on the EU market.

Large multinationals with an EU origin view themselves as a coordinator in the supply chain. They are not only machinery manufacturers, but also an active hub of information flows. They provide a wider range of products plus services. Furthermore, in the case of MRI devices manufacturing, multinationals attempt to use customer-orientation strategy and continuous technological input to reach a better equilibrium between the supply side and the demand side.

For non-multinationals, it is also challenging to deal with supply dependencies and supply risks. Even though it is hard to deal with challenges, when manufacturers are confronted with supply disruptions caused by severe unfavourable circumstances, there are ways to mitigate negative impact. Wider and more trustful networks, efficient manufacturing with less waste of CRMs, recycling technology, and risks sharing with suppliers from third countries can contribute to value creation. In addition, the tracking of customer demand and constant procurement and inventories are important for the business.

Content	MRI systems	YAG:laser	Cochlear device
Pillar 1: Geographical diversification of suppliers	Reduce dependencies on third countries at the processing stage. Increase raw materials sourcing opportunities and connection with suppliers in like-minded countries.	Improve reliability of supply chain relationships and reduce dependencies on a single third country at processing stage.	Only when the pertinent non-REEs CRMs could be sourced directly to the EU and or recycled in the EU, the policy brought a fundamental change.
Pillar 2: Mining and processing capacity building	Build connections with the mining and processing projects in the EU which are prepared to support medical imaging devices manufacturing. Increase the share of in-house material processing.	Move towards in-house raw materials processing in the EU. Reduce lead-time and improve manufacturing efficiency.	Could create opportunities for material processing in the EU in the future.
Pillar 3: Recycling and substitute materials	Build connections with companies with recycling techniques of niobium and neodymium in the EU and like-minded third countries. Push forward technological innovation of supporting facilities for substitute materials' application.	Improve processing techniques for secondary materials. Promote application of substitute materials and reduce costs.	Could reduce dependencies on key component manufacturers from the USA in the future.

Table 7: The behaviours of the EU's medical devices manufacturing in accordance with the three pillars of the Critical Raw Materials Act

Content	MRI systems	YAG:laser	Cochlear device
Pillar 1: Geographical diversification of suppliers	Synergic impact dependent on the extent of superconductor magnets substituting permanent magnets.	No impact if primary yttrium is still 100% controlled by a single country (China). Impact when choosing suppliers of substitute materials for neodymium.	Limited impact if the sourcing of CRMs is foremost decided by the key component supplier.
Pillar 2: Mining and processing capacity building	Synergic impact is limited due to mining's capacity in the EU.	Synergic impact on materials processing in the EU.	Synergic impact requires integration of all players in the supply chain. Manufacturers should be capable of produce key components.
Pillar 3: Recycling and substitute materials	Synergic impact dependent on recycling technology development of materials as well as in-company magnet recycling within the life cycle periode.	Impact when waste management of secondary yttrium works out, Well-functioned synergic impact on application of substitutes.	Synergic impact when recycling technology can be improved and commercialised.

Table 8: The future impact of three pillars of the Critical Raw Materials Act on the EU's medical devices manufacturing

To answer the first question, the EU Critical Raw Materials Act has a positive impact on independent development of European healthcare devices manufacturing. Geographical diversification of global suppliers, mining and processing capacity building, recycling and substitute materials can make further contributions to more variation and flexibility in the supply chain. For healthcare devices manufacturers, diplomatic efforts could make it possible for manufacturers to get access to resources like niobium. Furthermore, newly-established mining and processing projects in Europe could also provide rare earths and non rare earths materials to strategic industries including medical manufacturing. In addition, the EU-wide promotion for CRMs' recycling and discovery of substitutes will also contribute to medical manufacturing. We should notice that the EU's industrial strategic autonomy should be a fruit brought by both governmental and companies' efforts, a fruit based on accumulated political practice and business practice. The EU CRMs Act promotes the principle of open strategic autonomy which also has encouraged the self-promotion of the EU's CRMs' supply chain.

For the supply chain of the EU's medical devices manufacturing involving CRMs, depending on the circumstances, there will be an increasing participation of reliable suppliers for CRMs and processed materials, especially from the EU and like-minded countries. In addition, the EU's participation in the supply chain will be extended from the assembly stage to materials processing and recycling stage, even to the mining and refining stage for some materials. For the value chain of the EU's medical devices manufacturing, the impact of the EU's CRMs Act will root in the value creation process, combined with product innovation, technological application and computing support.

For the second question, to further adapt themselves to the opportunities provided by further policy instruments, the EU healthcare devices manufacturers should strengthen their positions in the supply chain as a coordinator or an influencer rather than merely a participant buying CRMs. Moreover, even though there is support from the policy side, business decision making should be based on actual situations, for instance, the manufacturing character of the product, the amount of CRMs needed, the input and output for any change in the supply chain pattern. Furthermore, the EU healthcare devices manufacturers should establish more connections with a growing number of European CRMs miners and processors in the future. Apart from business networking, there are also official networking platforms benefiting CRMs supply chain issues. In addition, a specific recycling system that is only for medical devices manufacturing is needed, as medical devices manufacturing does not accept recycled critical materials from other industries. All in all, if the healthcare industry adapts itself actively to the CRMs Act, it can get more benefits in the long run.

5. Conclusion

5.1. Conclusion

Critical raw materials are characterised by high economic importance and high vulnerability to supply disruption, and are geographically concentrated outside the EU (Blengini, G.A. et al., 2017). Potential risks of supply disruption might lead to severe consequences for the EU strategic industries. The enhancement of the EU industries' capabilities to mitigate supply risks is not only a task for the EU industries and manufacturers, but also relies on forceful policy instruments. Enforced policy instruments and legislation of policy can be a strong weapon to push the EU manufacturers forward.

For many technological manufacturers, sufficient critical raw materials is a guarantee for the value creation, because current and new technologies are core competencies for the company and commercialisation of technologies need critical raw materials for manufacturing. However, there are supply risks of critical raw materials for the EU industries because most of the resources are distributed outside the EU and some of the resources are highly concentrated in one or a limited number of countries. Uncertainty in geo-economic and geo-political circumstances might put pressure on the negotiation for critical raw materials. High dependencies on critical raw materials' supply could have a negative impact on the EU's economic resilience, when supply disruptions occur.

In the past several years, the CRMs issue has become a more and more important topic for the EU's resilience and strategic autonomy. With the political increasing concerns on CRMs issue, some companies have begun to realise the problem of supply risks and made attempts to reorganise the supply chain and tried to find other efficient ways for value creation. The Act is a great political support for the companies. It can motivate the EU's supply chain from CRMs' extractors and processors to components' manufacturers and to healthcare devices manufacturers. This motivation can bring changes throughout the supply chain of the EU healthcare industry. The Act aims to stimulate all possible internal and external motives to reorganise the supply chain and to boost the value chain for the EU industries.

The EU Critical Raw Materials Act is embedded with the current EU's principal strategy - open strategic autonomy - and aims to realise the EU's strategic autonomy in the supply chain, so that the EU can strengthen its leadership position in the global market. The legislation of the Act empowers policy instruments to support advanced industrial practice throughout the supply chain. The legislated Act sets regulations to support industrial strategic autonomy through multidimensional strategies on critical raw materials supplies, including 1) risk monitoring and mitigation, 2) capacity building and 3) circular economy and environmental sustainability (Hool, et al., 2023). The most relevant sub-issues for the healthcare industry are respectively 1) monitoring, strategic stocks and strategic partnerships. 2) strategic projects and national exploration requirements and 3) circularity (including CRMs recovery potentials, extractive waste recovery and permanent magnets).

The Critical Raw Materials Act is comprehensive and contains possible pathways to reduce supply chain dependencies on critical raw materials, which can inspire industrial practice from different dimensions to improve supply chain and value chain strategy. First, the Act can contribute to build and improve supplier communities for a variety of EU industries including medical devices manufacturing. Through diplomatic agreements and official partnerships building as well as some EU funded programs, more medical devices manufacturers can get access to reliable suppliers in the EU and from friendly third-countries. To some extent, greater networking with efficient information flow and constant stocks for further processing is a risk-sharing mechanism throughout the supply chain and eases the pressure and responsibility for the manufacturers. Second, mining, extraction and processing projects in the EU can build capacity for rare earths and non rare earths materials which can also be applied into medical devices like permanent magnets and superconducting magnets for the MRI systems, cochlear implants. However, when it comes to the business decisions, for instance, which product with which critical raw material should be more focused on, or whether sourcing from EU miners and processors or sourcing from like-minded countries, the questions are decided by the manufacturer. Third, policies on recycling and substitutes are very encouraging for the medical devices manufacturing. Some medical companies have already begun their plan for materials recycling and substitutes application. In addition, clear goals set by the policy will push forward relevant projects in the supply chain of critical raw materials. The supply chain of medical devices manufacturing will also get more benefits from the supply chain of critical raw materials.

To adapt itself to the three pillars of the Critical Raw Materials Act, the EU healthcare industry needs to enhance its capabilities in technological innovation, risk management, smart production and digitalisation. As many innovations on substitutes and new materials are led by the medical devices manufacturers, the application of substitutes and new materials and the change of supply chain strategy should be accomplished by the manufacturers themselves. Risk management should be based on the cooperation of manufacturers and suppliers and customers, for instance, a community of reliable suppliers and constant inventories, or a system for product management and upgrading. Moreover, manufacturers should be capable of accurate manufacturing products with more efficient input.

To summarise, the implementation of the Critical Raw Materials Act can continuously contribute to further innovation in the medical devices products and the further integration of the supply chain. The three pillars can encourage companies to explore internal and external resources in the supply chain. There are still a lot of capabilities for the EU healthcare industry to improve, so that the industry can seize the opportunities brought by the Critical Raw Materials Act.

5.2. Limitations and further research

The analysis does not cover all component types and technologies used in medical devices manufacturing, for example, semiconductors, 3D printing, robotics, batteries and computer technology. The components produced by these industries also contain a large amount of critical raw materials. Medical devices manufacturers may indirectly face supply shortage of critical raw materials from the suppliers in these industries. It should also not be neglected that the EU's dependency on critical raw materials is just one type of dependency on third countries. It is connected with other types of dependency, for example, the dependency on chip manufacturing from countries like the USA. If there will be an increasing supply of critical raw materials in the EU, local manufacturing for key components in the industries mentioned above will be motivated. It will also be a great support for the medical devices manufacturing, pharmaceuticals and healthcare service providers.

The master's thesis does not discuss much about the investment support for the EU capacity building. The investment on mining, processing and recycling projects in the EU is a considerable amount. Even though the procedure for getting governmental permission is regulated to be simplified, the procedure for receiving governmental funding for critical raw materials projects is uncertain. In addition, there are a lot of competitors from other sectors applying for a limited amount of national or EU fundings which has been planned for capacity building issues overall. In this thesis, we only use existing examples which have received financial support and are related to critical raw materials' supply chain.

This master's thesis chooses the EU healthcare industry as an example to explain the supply chain changes regarding critical raw materials in the context of EU open strategic autonomy and the increasing global geo-economic and geo-political dynamics. In fact, the EU Critical Raw Materials Act covers many industrial sectors and each industry has different ways of applying a wide range of critical raw materials into manufacturing. Despite similarities, there can be differences when it comes to the supply chain of different products using critical raw materials in different forms and amounts. Further research can study the supply chain of critical raw materials in other industries like energy and automobiles which are also mentioned in the EU Critical Raw Materials Act (Article 2 of the CRMs Act).

Recently, an amount of critical raw materials reserves have been explored and factories have been established. However, the geographical distribution of resources is not equal in the EU. It means that the EU countries with access to these resources have new resources for national income and better chances to build capacity. However, how much of the resources are used to satisfy related industries in the home country and how much of the resources can be sold to other EU countries, the answer is uncertain. It is the same case with components manufacturers. Non-multinationals may focus only on the national market and the market of neighbouring countries.

Further studies can focus on the establishment of an EU-wide integrated industrial supply chain including critical raw materials producer, key component producer, end-product manufacturer, customer, collecting and recycling of critical raw materials. Another focus is cost efficiency study for a certain product sector or a certain industry. To implement the policy of recycling and substitute or procurement of critical raw materials from a new partner country, innovative value generation methods should be recognised and proven to be suitable in the long run.

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