Master Thesis
The potential effects of the EU-Japan Economic Partnership Agreement on Swedish MedTech

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Abstract
The new economic partnership agreement (EPA) between the European Union (EU) and Japan is the most extensive free trade agreement the EU has ever had. It came into force on February 1st in 2019 with some immediate changes and some changes that will be implemented over the coming years. It is yet hard to tell what extent it will affect involved sectors and industries. The purpose of this master thesis project was to discover the effects for Swedish companies, that are either already established on the Japanese market or that are considering entering it.

In order to narrow down the scope a focus on the MedTech industry was selected. The empirics were collected through ten case studies in Japan. Five case studies with different companies and five case studies with different organizations.

The studies showed that two of the greatest direct effects of the agreement, public procurement and tariff reduction, will not affect the MedTech industry to any large extent. Hence the effects of the EPA for the MedTech industry will mostly be indirect. The authors have identified the product approval process as the largest obstacle for foreign MedTech companies conducting business in Japan. The EPA could potentially harmonize the process further. Lastly, in order to reach a high rate of utilization of the EPA, it is important that the actors involved in the development and implementation of the agreement manage to disseminate information and educate companies. In turn, it is important for companies to drive the implementation of the agreement forward.

Keywords: Case study, European Union, Swedish companies, MedTech, Free trade agreement, Economic partnership agreement, EPA, Japan, harmonization, trade
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Anton Lundqvist
Lund, January 2019

Martin Persson
Lund, January 2019
Executive Summary

Title
The potential effects of the EU-Japan Economic Partnership Agreement on Swedish MedTech

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Background
On the 1st of February in 2019, the European Partnership Agreement, EPA, between the EU and Japan was put into power. The agreement aims to stimulate trade between the economies by reducing thresholds to trade. Japan is one of the largest markets in the world for medical devices, MedTech, but is also one of the most regulated. Sweden has a strong MedTech industry and Japan is an important market. What effect will the EPA have on the Swedish MedTech companies?

Purpose
The purpose of the master thesis project is to determine what effects the EU-Japan Economic Partnership Agreement will have on Swedish MedTech companies. The intent is to map out which parts of the agreement that has had or will have the largest impact for already established companies and for potential entrants. Lastly, it intends to investigate how much the companies know about the EPA and how much they have adjusted their business in order to utilize it.

Research questions
The research questions this master thesis project intends to answer have been divided into two main questions and in total five sub-questions.

1. What are the current effects of the EU-Japan EPA on Swedish MedTech companies in Japan?
   a. What are the positive effects?
   b. What are the negative effects?
   c. Efforts to utilize the agreement?
2. What future effects may EPA have on Swedish MedTech companies in Japan?
   a. For companies already established on the market?
   b. For potential entrants?

Delimitations
The master thesis project is delimited to examine the effects of the EPA on Swedish MedTech companies. This means that it will not seek to answer the question of how the entire industry will be affected, even though it is likely that the effects from the EPA will be similar to all EU MedTech companies, regardless of country. MedTech companies are in this project defined as companies that sell products that are categorized as medical devices in Japan.
Method
This master thesis project is of exploratory nature and uses case studies to obtain qualitative, primary data from 10 different actors through interviews. Furthermore, the approach is abductive, meaning that theory is built partly on learnings from the interviews.

Conclusions
The authors have identified the long, complex and expensive product approval process as the biggest obstacle for Swedish MedTech companies in Japan. Furthermore, they have concluded that this obstacle is the one the EPA will affect the most. The effects from the EPA can be divided into two areas:

- Firstly, before the EPA was agreed upon, EU and Japan negotiated several non-tariff related barriers. One of these barriers was an outdated law for medical devices and pharmaceuticals. In 2014 a new law was implemented, leading to a less complex, less expensive and shorter product approval process for medical devices.
- Secondly, several interviews witness of a changed attitude from the Japanese government over the last couple of years. It now seems as if the Japanese government is more willing to solve trade thresholds in general and to listen to industry-related problems and to issues driven by lobbying organizations.

Regarding the level of knowledge, the companies possess concerning the EPA, the authors have concluded that it is relatively low for Swedish MedTech companies. It is however not surprising considering EPA does not explicitly target the MedTech industry and that effects from it are of indirect nature. Furthermore, the authors have concluded that none of the Swedish MedTech companies have made any major efforts in order to utilize the EPA.

Regarding the opportunities for potential entrants, the authors have concluded that the business climate for Swedish MedTech in Japan has not dramatically improved due to the EPA. Should the product approval process be further harmonized, opportunities for entrants would improve, but it is uncertain if and when this would happen.
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List of Abbreviations

APAC – Asia-Pacific Countries
DCFTA – Deep and Comprehensive Free Trade Area
DG – Directorates-General
EBC – European Business Council
EMA – European Medicines Agency
EPA – Economic Partnership Agreement
FTA – Free Trade Agreement
GDP – Gross Domestic Product
GPA – Agreement on Government Procurement
GMDN – The Global Medical Devices Nomenclature
IVF – In Vitro Fertilization
METI – Ministry of Economy, Trade and Industry
MHLW – Ministry of Health, Labour and Welfare
NTM – Non-Tariff Measure
NTB – Non-Tariff Barrier
PMDA – Pharmaceuticals and Medical Devices Agency
PMDL – Pharmaceutical and Medical Devices Law
QMS – Quality Management System
RTA – Regional Trade Agreement
SCCJ – Swedish Chamber of Commerce and Industry in Japan
SME – Small and medium enterprise
WTO – World Trade Organization
1. Introduction

This segment begins with the background, which aims to give the reader an overview of free trade agreements, EU and free trade agreements, Japan's economic development and lastly EU-Japan relations. The background is continued by the choice of topic, followed by delimitations, purpose and research questions.

1.1 Background

1.1.1 Free Trade Agreements

A free trade agreement (FTA) is an agreement between two or more parties with the purpose of reducing obstacles, such as tariffs, duties or regulatory trade obstacles (Barone, 2019). It is however not necessarily an agreement in which all obstacles are scrapped. For different reasons, such as to protect local production of a certain type of goods, parties in the agreement can choose to maintain some of the thresholds, making the trade easier but not completely free. FTAs are authorized by the World Trade Organization (WTO) and need to comply with their legislation (World Trade Organization, n.d.).

FTAs indeed do stimulate trade, but they are not problem-free and there exist different opinions regarding whether they are wanted or not (Barone, 2019). A free trade agreement could be seen as an opportunity for a country to produce and export what it is good at and import what it is not good at. On the other hand, an FTA means unfair competition for countries not involved in the agreement, by scrapping customs or duties for example. For the countries involved however, FTAs have proven to have a positive effect on trade in general (National Board of Trade Sweden, 2018, p. 1).

Today, the global business climate seems to be characterized by protectionism with Brexit and the trade conflict between the US and China. However, the number of bilateral and regional free trade agreements is increasing rapidly all over the world (National Board of Trade Sweden, 2018, p. 1).

1.1.2 EU and Free Trade Agreements

The first FTA the EU entered was an agreement with Iceland on the 31st of December in 1972, this was shortly after followed by a second FTA with Norway on the 27th of June in 1973 (European Commission, 2019). Since then, the EU has entered into a wide range of FTAs. Today, the EU has 35 major agreements, including 62 different parties (European Commission, 2019, p. 7).

The purpose of the EU to enter FTAs with other parties varies depending on the type of agreement. In general, it is to boost trade by removing barriers to trade. In addition, they are a channel for the EU to spread values concerning workers’ rights and environmental protection, as well as to enhance economic diversification and growth in developing countries. (European Commission, 2019, p. 42)
The EU has grouped its FTAs into four categories:

1. **First-generation agreements** focus on tariff elimination. These types of agreements have been entered with, amongst others, Norway and Switzerland.

2. **New generation agreements** are an extended version of the first generation and include areas such as intellectual property, sustainable development, public procurement, and regulatory issues. The EU has entered new generation agreements with, amongst others, South Korea, Colombia, and Canada. The newest agreement of this category is the EU-Japan Economic Partnership Agreement (EPA), which also includes chapters concerning modern challenges in economies and societies. The EU-Japan EPA is more thoroughly described in the theory section.

3. **Deep and Comprehensive Free Trade Areas (DCFTAs)**, focus on enhancing economic relations through harmonizing legislation issues. Amongst others, the EU has DCFTAs with Ukraine and Moldavia.

4. **Economic Partnership Agreements with developing countries** are asymmetric agreements with the aim of boosting the other party’s economy through granting duty and quota-free access. The EU has entered this type of agreement with countries in Africa, in the Caribbean and in the Pacific. (European Commission, 2019, p. 8)

1.1.3 Economic Development of Japan

After the second world war, Japan had lost about 4% of its population and materials worth about 25% of the national wealth (Otsubo, 2007, p. 4). Almost all industries faced a heavy decline and the country was in a tough economic situation. Few could have thought that it would rise to be the second-largest economy in the world by 1978, a ranking which they held until 2010 when they were surpassed by China. This post-war era was later referred to as the Economic Miracle and can be divided into four stages: the recovery phase, the high increase phase, the steady increase phase and the low increase phase (Kiprop, 2019). The recovery phase ranged from 1946-1954 and was centralized around rebuilding coal, cotton, and steel industry. In addition to this, the government developed a system to fund these industries in order for them to achieve rapid economic growth (Otsubo, 2007, p. 5). After the initial recovery, Japan entered into a period of rapid growth. During this period from 1954-1972, Japan rose to be one of the highest developed countries in Asia. The growth was mainly a result of the prospering heavy industry, such as energy, machinery and chemicals. These types of industries were highly favored in governmental investments, which caused a big gap between them and the industries that were not. This was often criticized by the general public but could be managed through the fact that the rapid economic growth was able to raise the living standards in all of Japan (Otsubo, 2007, p. 13). The steady growth phase reach from 1973-1992, through this phase Japan managed to grow its economy even through the 1973 oil sanctions that affected large parts of the world (Kiprop, 2019). In the early 1990s, the bubbles, that had been build up through excessive loans and employment, burst. First the bubble of the stock market and then the bubble of the real estate market (Otsubo, 2007, p. 5). Two years after the bubble of the real estate burst, in 1994, Japan had a GDP of 4,9 trillion USD. The growth has been fluctuating heavily since then. In 2012 they had a peak of 6,2 trillion USD, after which it decreased again and dropped to 5,0 trillion USD in 2018 (Kiprop, 2019). One reason behind the decline is the aging and decreasing population of Japan (Dormido & Takeo, 2019). By 2020 it is expected that 30% of the population will be above 65 years old. This trend is not likely to change
in the near future as the birth rates are low and immigration is basically non-existent. In addition, people are moving into big cities, depopulating the countryside.

Today, with a population of 127 million people and a GDP of 5 trillion USD, Japan is the third-largest economy in the world. Japan is investing a lot in R&D and they are the second country in the world with the most patents in force (The Government of Japan, n.d.). Both Sweden and Japan spend approximately 11% of their GDP on healthcare (Business Sweden Tokyo, 2019).

1.1.4 EU-Japan Relations

In 1970, the first attempt to establish a trade agreement between the EU and Japan was made. Japan had regained their independence in 1952 and was, alongside Canada, the US, Australia and New Zealand classified by the EU as an industrialized country (Tanaka, 2013, pp. 510-514). The negotiations failed shortly after they were initiated, and the following time period was characterized by trade conflicts between the economies. About 20 years later, Japan reached out to the EU to start up a new agreement with the goal of building a relation. In 1991, a Joint declaration on EU-Japan relations was signed in The Hague. One of the aspects agreed upon was to have annual summits. In December 2001, the cooperation advanced as the *Shaping our Common Future: An Action Plan For EU-Japan Cooperation* document was signed. This document focused on peace and security, trade, global societal changes and bringing people and cultures together. Following this document, five additional agreements were signed: EU-Japan Mutual recognition agreement in 2002, Agreement on Co-operation on Anti-competitive Activities in 2003, Agreement on Co-operation and Mutual Administrative Assistance in 2008 and Science and Technology agreement in 2009 (European Commission, 2019). In 2011, the EU and Japan decided to look closer at how to further integrate the economies through an EPA (Tanaka, 2013, pp. 510-517). This was partly initialized as a result of the EU entering an FTA with Korea, giving the Korean automotive industry a competitive advantage over the Japanese. Additionally, it was an effect of an analysis concluding that there was a large untapped potential in terms of trade between the economies (European Commission, 2018, pp. 6-8). The obstacles identified were tariffs/duties/customs and non-tariff differences such as regulations. The negotiations for an EPA was initiated in March 2013 and were finalized on the 8th of December in 2017. The EU-Japan EPA was put into power on the 1st of February in 2019 and its details will be further described in the theory section.

Today Japan is one of the most important strategic partners for the EU (European Commission, 2018, p. 6). The two economies share values of fair trade, of free trade, of democracy and have strong political and economic links. In 2018, the EU exported around 65 billion USD worth of goods to Japan, which employed about 600 000 people (European Union External Action, 2019, p. 1). For Japan, the numbers were similar, exporting 70 billion USD worth of goods and employing half a million people in the EU. As for services, the EU exported 34,7 billion USD worth of services to Japan and Japan exported 18,3 billion USD worth of services to EU in 2017.

1.2 Choice of Topic

This master thesis project intends to explore the effects of the EPA on Swedish companies selling products classified as medical devices on the Japanese market, hereafter Swedish MedTech.
The agreement from an EU perspective aims to: Remove tariffs and reduce thresholds to trade, shape global trade rules in line with the high standards and values of the EU and to send a signal of rejection against protectionism (European Commission, 2019). When fully implemented, 97% of goods exported from the EU to Japan will be duty-free. Other trade obstacles addressed are regulations and technical standards, with the intent to enable EU-companies to access the highly regulated Japanese market (European Commission, 2019). The European Commission is expecting that the agreement will have an extra-large impact on some industries in particular; Life Science, Food and beverages, Equipment for transportation and Vehicles (Business Sweden, n.d.). Out of these industries, Life Science was initially chosen as research topic out of interest of the authors in combination with the fact that the Life Science industry is big in Japan. In this report, Life Science is defined as the three industries combined: MedTech, Pharmaceuticals, and BioTech. Early on, the authors chose to narrow down the scope further and focus on MedTech as MedTech is a heavily regulated industry, making it a relevant industry to analyze in terms of how the reduction of obstacles to trade will affect future business (Pacific Bridge Medical, 2018). Swedish MedTech companies in specific were chosen to guarantee that a sufficient amount of data could be collected, by utilizing the network of Business Sweden, the Swedish Chamber of Commerce and Industry in Japan (SCCJ) and the Swedish Embassy, which all have strong connections with the Swedish companies operating on the market (European Commission, 2016).

In addition to the aspiration of helping Swedish companies, the project intends to provide insights of Economic Partnership Agreements in general which could be of value for similar free trade agreements in the future.

1.3 Delimitations

In this master thesis project, Life Science is defined as a combination of the three industries: Pharmaceuticals, MedTech and BioTech combined, see figure 1. The authors intend to examine the potential effects of the EPA on Swedish MedTech companies, meaning that no research regarding the overall MedTech industry or the Life Science industry will be done. Swedish MedTech companies are in this project defined as companies that sell products that are categorized as medical devices in Japan. Furthermore, this master thesis project will not examine the ethical dilemmas of free trade agreements in general.
In the figure below the delimitation of the focus of the master thesis project is illustrated.

![Diagram](image)

*Figure 1: An illustration of the delimitation of the focus for the master thesis project (author's).*

1.3.1 Target Audience

This thesis is aimed at students, researchers, Swedish MedTech companies and people working in organizations connected to the EPA. As the target audience is wide and possesses different types of background knowledge, readers might find certain sections more or less complex. The overall level is however aimed to fit all targeted groups.

1.4 Purpose

The purpose of the master thesis project is to investigate the potential effects of the EPA on Swedish MedTech companies. To achieve the purpose, extensive data collection through interviews with companies in the industry, and with companies and organizations of relevance, will be performed. The data will be used to map out which parts of the agreement that has had or will have the largest impact for already established companies and for potential entrants. Additionally, the authors will investigate how much the companies interviewed knows about the EPA and how much they have adjusted their business in order to utilize it.

1.4.1 Project Objective

The objective of this project is to provide the Swedish MedTech industry and other stakeholders with insights into the effects from the EU-Japan EPA. This includes the current effects as well as the potential future effects. The Swedish MedTech companies in Japan will be in focus but the objective is to enlighten the entire Swedish MedTech industry.

1.5 Research questions

The research questions this master thesis project intends to answer have been divided into two main questions and in total five sub-questions.
1. What are the current effects of the EU-Japan EPA on Swedish MedTech companies in Japan?
   a. What are the positive effects?
   b. What are the negative effects?
   c. Efforts to utilize the agreement?
2. What future effects may EPA have on Swedish MedTech companies in Japan?
   a. For companies already established on the market?
   b. For potential entrants?

Above are the research questions for the project, which have been developed to be as mutually exclusive and collectively exhaustive as possible.

1.6 Report structure

Chapter 1 - Introduction
In this chapter, background information on the research topic is provided. Furthermore, choice of topic, delimitations, purpose, project objective, and research questions are presented.

Chapter 2 - Method
In this chapter the method of the project is described; research purpose, research strategy, research approach, research design, analysis & conclusion and lastly quality of research.

Chapter 3 - Theory
In this chapter the theory is presented; the EU Japan EPA, overview of the MedTech industry in general and Swedish MedTech in specific and actors relevant for the EPA.

Chapter 4 - Empirics
In this chapter, the empirics are presented. The empirics are divided into three cases: MedTech companies, Life Science companies, and Organizations connected to the EPA/or the MedTech industry. Lastly, an overview of the empirics is presented.

Chapter 5 - Analysis
In this chapter, the analysis of the empirics and theory is presented. The analysis is divided into three cross-case analyses, one for each case: MedTech companies, Life Science companies, and Organizations connected to the EPA/or the MedTech industry. Lastly, a cross-case analysis between the three is presented.

Chapter 6 - Discussion
In this chapter implications and insights from the analysis-chapter are discussed.

Chapter 7 - Conclusions
In this chapter, the conclusions of the project are presented. The chapter is divided into a summary of conclusions, answers to the research questions, the fulfillment of purpose, further reflections, suggestions for further research and lastly contributions to research.
2. Method

*In this part the chosen methodology for the research is presented together with how the quality of the research is guaranteed. The purpose and the strategy of the research are included, as well as the adjustments that had to be made during the execution of the research. Different methods and approaches are introduced, and the chosen ones are motivated.*

2.1 Research Purpose

A research can have four different purposes; *Descriptive, Exploratory, Explanatory and Problem Solving* (Höst, et al., 2006, p. 29). What differs between them is what the researcher aims to achieve by performing the research. A descriptive approach aims to describe how something works or is performed, an explanatory approach aims to map out cause and effect and explain how something works or is performed, a problem-solving purpose is to solve an existing problem and an exploratory approach aims to in-depth understand how something works or is performed. This master thesis project intends to map out the potential effects of the EPA on Swedish MedTech companies in Japan. However, to succeed in this, it is necessary to in-depth understand how the EPA and its different actors are intertwined. The purpose of this project is therefore of exploratory nature.

According to Lekvall and Wahlbin, an exploratory purpose is suitable when it is not quite clear which aspects are the most relevant to delve into, or which courses of actions are available (2001, pp. 196-197). An exploratory research can in these cases assist in building a rigorous foundation of knowledge in the area of interest and to generate ideas for courses of action.

2.2 Research Strategy

There are mainly four different research strategies that can be used when conducting a master thesis project: Survey, case study, experiment or action research. A survey is a summary and a description of the current state of the studied issue. A case study is an in-depth study of one or multiple cases where you try to avoid affecting the issue you study. Experiment is a comparing analysis between two or multiple alternatives where you try to isolate a limited number of factors and then manipulate one of them. Action research is a closely overviewed and documented study of an activity which intent is to solve a problem.

In this master thesis project, case study/sub case studies (see 2.4.2) were performed since the purpose was to in-depth analyze the effects of the EPA. The design of a case study is flexible which means that it is possible to change questions and the direction during the course of the study (Höst, et al., 2006, p. 34).
2.3 Research Approach

2.3.1 Qualitative Versus Quantitative Data

The difference between qualitative and quantitative data is mainly how the data is collected & expressed. Qualitative data tends to often be expressed in words whereas quantitative data is more commonly expressed in numbers. Additionally, what separates the two types of data is what type of initial analysis is performed on it: Is it of statistical or verbal reasoning nature? A few characteristics for qualitative data are: Small and non-random selection of respondents, relatively unstructured interviews, a larger effect of the interviewer's subjectivity than in a process of retrieving quantitative data, and lastly – less complex data to understand, often expressed in everyday language. (Lekvall & Wahlbin, 2001, pp. 213-215)

The process of gathering data has been conducted through a small selection of non-randomly selected cases, using a semi-structured form of interviewing. It could be argued that through having a hypothesis of the EU-Japan EPA having a positive effect, the interviewees indeed are exposed to a certain degree of subjectivity. The data is presented in an uncomplex form, accessible for a wide audience. The data analyzed in this project is therefore of qualitative nature.

The critique against qualitative analyzes argues that conclusions appear to be arbitrary and subjective. However, as many quantitative analyzes are also exposed to subjectivity, the division between the two should not be done simply by looking at whether the data is in numbers or words, but rather in what form the analysis has been done (Lekvall & Wahlbin, 2001, pp. 213-215). The analysis and the interpretation of data are explained below in the parts Analysis and Conclusions.

2.3.2 Inductive, Deductive or Abductive Approach

There exist three different approaches on how to reason with existing knowledge: Inductive, deductive and abductive approach. With an inductive approach, a theory is created by collecting and analyzing a set of data (Brinkmann, 2013, pp. 53-56). Qualitative research is most often categorized as inductive since the researchers many times enter a field and start collecting data to see what issues might be of interest to seek an answer to. With the deductive approach, theories are tested by trying to falsify them. The challenge when using this approach is for the researchers to make a decision when a case is contradicting the theory, to reject the theory or to ignore the observation. Both the inductive approach and the deductive approach work best when the researchers are studying something that they already have some knowledge about. However, when the scope is uncertain an abductive approach is to prefer. Instead of going from theory to data or from data to theory, an abductive approach combines them and moves back and forth between theory and data (Saunders, et al., 2015, p. 148). See figure 2 for an illustration of how the abductive approach was used in the process of the research.

Since the EPA came into force only seven months before the data collection, it does not yet exist a lot of studies on the effects of the EPA, and even less on the effects on Swedish companies. The research was therefore conducted using an abductive approach where the authors iterated between theory and what was learned in the data collection. By using this method, the authors
could also analyze the data throughout the whole research in order to get a head start in the analysis. However, in order to start building a theoretical foundation before the start of the data collection, the authors consumed reports and articles about the agreement, many of which were from the European Commission.

In the figure below the research process with the abductive approach is illustrated. The grey arrows illustrate how the authors moved between the different steps in the process.

![Figure 2: An illustration of the research process with the abductive approach (author’s).](image)

2.4 Research Design

2.4.1 Research Technique

In order to collect the data needed for the project, interviews were conducted. Interviews differ depending on the level of structure that is being used: open directed, semi-structured and structured (Höst, et al., 2006, p. 34). In an open interview the interview guide consists of “question areas”. The person being interviewed decide how much time he or she wants to spend within one question area. The order of the question areas and the formulation of them can vary from one interview to the next. This is useful if the purpose is to let the interviewee decide what to talk about. In semi-structured interviews, open directed questions are mixed with fixed questions. The fixed questions have to be asked with the same formulations and in the same order in every interview. The structured interview consists only of fixed questions and is basically an oral survey.

In this project, a semi-structured approach was used in the interviews, due to the high level of difference regarding the interviewee’s knowledge of the research area. The interview guides were fitted according to the kind of company or organization and followed to different degrees depending on the answers from the interviewee.

During the research a feedback-loop was established in which interviews analyzed and the learnings contributed to the remaining case studies. The throughout the interviews was to deepen the understanding of the EPA and the aspects that were of importance for the MedTech industry. One challenge with this type of approach is that it is difficult to not get overwhelmed by the amount of data. Eisenhardt mentions that it is important to be well prepared and to have a well-defined focus before executing the interviews (1989, p. 536). Hence it was always a balance of finding the right focus in order not to get overwhelmed by data.
The execution of the interview can be divided into four phases consisting of: Context, warm-up, main questions and summary (Höst, et al., 2006, pp. 91-92). In the context phase the interviewers describe the purpose of the interview and what they hope to achieve with this particular interview. In the warm-up phase, it is important to have a few easy and neutral questions that give straight answers in order to get the conversation going. The main questions should be asked in an order that seems logical for the person being interviewed. Finally, in the summary, the interviewer concludes what has been said in the interview and the person that has been interviewed gets a chance to correct or add information. This structure was mainly followed during the interviews. However, many of the interviewee’s were high ranking officials and therefore the interview guide at times had to be compressed due to time limits. In these cases, the summary was not prioritized.

During the interviews, field notes were made, and the interviews were also recorded by one of the authors’ cellular devices. The field notes were afterward compiled with the assistance of the audio recording. The recorded audio was of great help in terms of being able to revisit previous interviews as the theory of the project was developed. Full transcriptions were not made. Both authors were present on all the interviews in order to increase the likelihood of capitalizing on novel insights by having complementary insights and different perspectives. In the interviews, the authors had different roles. One of the authors was assigned the role of interviewer and one was assigned the role as an annotator. As recommended in the literature, the author with the role of an interviewer had more of a personal interaction with the interviewee and the author with the role as an annotator kept a more distant view. However, the annotator occasionally intervened by asking follow-up questions to the interviewee. The roles were not interchanged over the course of the data collection phase, in order to make the performing of the interviews as similar to each other as possible. (Eisenhardt, 1989, p. 538)

2.4.2 Case Selection
In order to be able to draw accurate conclusions concerning the potential effects of the EPA, multiple cases were selected. The goal of theoretical sampling was to choose cases that were likely to replicate or extend the emergent theory (Eisenhardt, 1989, p. 537). The authors therefore strove to get in contact with as many Life Science companies and organizations connected to the EPA and/or the MedTech industry as possible. One factor limiting the amount of cases that eventually were examined, was that the authors had to go through the networks of SSCJ and Business Sweden and could not contact the companies on their own. When the scope eventually was narrowed down to Swedish MedTech companies, the authors chose to not discard the cases that were Life Science companies but not Swedish MedTech companies, as they were considered valuable for the research. The reason for including organizations connected to the EPA and/or the MedTech industry was gather knowledge of the negotiation and implementation of the EPA, in addition to getting new perspectives on potential effects.
The cases selected were divided into sub-cases and those were sorted into three different categories:

1. **MedTech companies**
   - Elekta
   - Mölnlycke
   - Vitrolife

2. **Life Science Companies**
   - Mentice
   - Pharma Consulting Group

3. **Organizations connected to the EPA and/or the MedTech industry**
   - Embassy of Sweden
   - Business Sweden
   - European Business Council
   - Delegation of the European Union to Japan
   - Centre for Industrial Cooperation

The list above contains the different cases/sub-cases for the study.

### 2.5 Analysis & Conclusions

When the data collection was done, and the sub-case studies were finished, the results from the different cases were compiled in three different matrices, one for each category. This was done in order to create a structure of the collected material and to make a step of data analyses.

By using the matrices, the empirics were analyzed in two steps. First, a cross-case analysis between the cases in each of the three categories was made. In these cross-case analyses, the data were analyzed by comparing and triangulating the different findings between the cases. After completion, an analysis between the cross-case analyzes of the different categories was made: a cross-cross analysis. Here the findings from the MedTech companies, the Life Science companies and Organizations connected to the EPA and/or the MedTech industry were compared.

When the analyses were completed, the findings were discussed together with relevant theory and thoughts of the authors. Conclusions were then summarized.

### 2.6 Quality of Research

The quality of the research can be assessed from three different perspectives; reliability of data collection and analysis with regards to random variations, validity by measuring what is supposed to be measured, and representativeness by making general conclusions. (Höst, et al., 2006, p. 41)

In order to achieve a high degree of reliability, it is essential to be thorough in the data collection and in the analysis (Höst, et al., 2006, p. 41). This was achieved through assistance from organizations connected to the EPA when selecting which cases to study. Additionally, all data gathered during the interviews was sent back to each person that had been interviewed to confirm that the empirics were correct. The degree of reliability of the analysis is high due to the
convergence of observations from two different researchers, compared to if it only would have been one (Eisenhardt, 1989, p. 538).

Validity is about the connection between the studied object and the actual studies performed (Höst, et al., 2006, p. 42). A high degree of validity can be achieved by triangulating the data. Triangulating data is done by studying an object with different methods. In this research validity was ensured by asking several actors the same questions about the EPA.

In general, it is not possible to make general conclusions from case studies (Höst, et al., 2006, p. 42). However, the degree of representability can be increased by a good and thorough description of the context of the study. Therefore, the authors put a lot of effort into the background and the theory sections of the project. Also, by performing multiple case studies the degree of representability is increased.

2.7 Research ethics

The authors have taken several precautions throughout the master thesis project to ensure an ethically correct research. The main risks considered were associated with performing, transcribing and summarizing the interviews. To mitigate these risks, every interviewee was asked before each interview to consent to participation and whether to be anonymized or not. Additionally, before each interview permission to record the interview was asked for. Finally, each interviewee was sent the transcribed interview, giving them a chance to correct misinterpretations.

The ethical aspects of free trade agreements are debated, some say that they are highly problematic as they contribute to unfairness in competition, amongst other things. Others have a more positive view. The authors do not cover ethical dilemmas of free trade agreements due to two reasons: firstly, it being a subject big enough on its own to make up for a master thesis project, and secondly: it is considered not to assist the authors on their quest to answer the research questions.
3. Theory

In this part, the theory in order to understand the empirics is put together. First, the EU-Japan agreement is described in more detail, then the MedTech industry is covered: the industry in general, EU-level, Japan and lastly Swedish MedTech. Furthermore, the actors of relevance are described.

3.1 The EU-Japan EPA

The Economic Partnership Agreement between the European Union and Japan, or the “cars-for-cheese” agreement as many commentators have called it, came into force on February 1st in 2019. The purpose of the agreement is to remove barriers for export and import between the economies, shape global trade rules and send a message of rejection towards protectionism (National Board of Trade Sweden, 2018). Some changes have already been implemented and some will be implemented gradually over the coming years. The agreement is expected to be fully implemented by 2035 and the changes are expected to increase the GDP of the EU with 33 billion euro and the GDP of Japan with 29 billion euros (European Commission, 2018). However, the percentage increases are 0,14% and 0,61% respectively. The impact on the bilateral exports will be 13,5 billion euros (a 13,2% increase) for the EU and 22,2 billion euro (a 23,5% increase) for Japan. The European Commission is expecting that the agreement will have an extra-large impact on some industries in particular; Life Science, Food and beverages, Equipment for transportation and Vehicles (Business Sweden, n.d.).

The reason it is called the “cars-for-cheese” agreement is that the tariff for European cheese of almost 29% will be scrapped over a period of 15 years and the 10% tariff on Japanese cars will be scrapped over a period of 10 years (European Commission, 2018). The reason for having a gradual reduction of tariffs is to soften the impact on products that are considered sensitive. Overall the agreement will lead to a great liberalization. The EU has liberalized 99% of tariff lines and Japan 97% of tariff lines. Japan have compensated for the lower level of liberalization of tariff lines by dealing with a large number of NTMs. The EPA also includes one part regarding SMEs, with the goal to make it possible for them to make full use of the EPA. In this part, it is also stated that the EU and Japan are obliged to provide the SMEs with the information about the agreement that might affect them.

It is unclear exactly what the effects of the new agreement will be. The most concrete effects are tariff reductions, but the greatest potential lies within the removal of the non-tariff related trade barriers, like increased cooperation when it comes to technical standards and more access to public procurement (Business Sweden, n.d.). Predictions of the future are more easily done in some industries than in others, for example, the vehicle industry has already agreed upon many of the technical standards (European Commission, 2018). According to Business Sweden, technical standards and other non-tariff trade barriers will require hard work by companies, stakeholders and authorities to agree upon (Business Sweden, n.d.). As Cecilia Malmström, former EU Commissioner of Trade, put it: “It is now up to businesses and individuals to make the very most out of these new trade opportunities. We also count on all EU Member States to spread this message far and wide.” (European Commission, 2019).
3.2 The MedTech industry

3.2.1 Overview

The MedTech industry is a diversified industry with products that range from high technological products like X-ray scanners to simple consumables like sticking plasters. According to The Global Medical Devices Nomenclature (GMDN) Agency, who are responsible for identifying medical devices, the sector includes more than 500 thousand technologies and 20 thousand generic groups that fall within 16 categories of products (GMDN Agency, n.d.) (European Commission, 2016). Generally speaking, the devices are used to diagnose, prevent, monitor and treat illness, as well as to overcome disabilities (European Commission, n.d.).

3.2.2 The MedTech Industry in the EU and Japan

Japan is the second-largest country when it comes to exporting medical technology (MedTech) for the EU (European Commission, 2016, p. 177). In one of the studies, performed during the negotiations of the EPA, the MedTech industry was considered to be a sector with one of the highest levels of gains when it comes to regulatory issues. According to one report from business Sweden, Japan is one of the world’s most attractive markets for medical devices due to its large population and their compulsory Healthcare insurance system (Business Sweden Tokyo, 2019). However, it is also one of the highest regulated industries and it is not just their approval process that is different, but also their definitions of what is considered a medical device. For example, in Europe nasal sprays are classified as a medical device but in Japan, it is classified as a pharmaceutical (European Commission, 2016, pp. 178-180). What is special about this industry is also the high degree of SME participation, with 10 000 companies in the EU and 1000 in Japan. Both the EU and Japan use a risk classification system to classify medical devices. Both systems consist of four different levels and they are similar to a large extent.

In the EU the sector employs 675 thousand people in Europe and has a yearly turnover of 110 billion euro (European Commission, n.d.). In the EU the medical devices are regulated by national authorities and in certain categories also by the European Medicines Agency (EMA) (European Medicines Agency, 2019). The products have to comply with legal and safety requirements and are marked with the CE (Conformité Européenne) mark when they have passed the assessment required. The CE mark is used in the European Economic Area and signals that the product has been assessed to meet high safety, health, and environmental protection requirements (European Commission, n.d.).

In Japan, the market for medical devices is worth 37 billion USD and it is growing approximately three percent per year (Business Sweden Tokyo, 2019). However, there exists a “device gap” compared to the number of products that are available in the EU and the US (European Commission, 2016, p. 176). This is due to existing barriers that make the export of new devices to Japan costly and time-consuming. In Japan, the Ministry of Health, Labour and Welfare (MHLW) work together with the Pharmaceuticals and Medical Devices Agency (PMDA) in the approval process of new medical devices (PMDA, n.d.). It is the registration process that is complex, costly and time-consuming (THEMA, 2019). It usually takes 1-3 years, depending on
the complexity of the product to get an approval. The process was however previously longer,
more expensive and more complex. Advancements were made on the 25th of November in 2014 when Japan launched a new law on pharmaceuticals and medical devices called the
Pharmaceutical and Medical Devices Law, hereafter PMDL (European Commission, 2016, p. 166). PMDL affect all parts of the Japanese product registration and replaced the previous law called Pharmaceutical Affairs Law (Pacific Bridge Medical, 2018). As part of the PMDL, Japan adopted the international standard on quality management systems (QMS) (European Commission, 2018, p. 24). This significantly reduced the costs of certification for European products since the EU QMS system for medical devices is based on the international standard.

3.2.3 Swedish MedTech

Sweden has an innovative business climate which has resulted in several Swedish MedTech inventions: the pacemaker, the ultrasound and the synthetic kidney (Swedish medtech, n.d.). Sweden is a hub for international MedTech businesses, not only due to the innovative climate but also due to the Swedish demography. Sweden faces the problem of an aging population, meaning an increase of people in need of medical care and a decrease of people to look after them. The demand for products that can treat and relieve pain from patients and thereby reduce the heavy workload of nurses and doctors is therefore growing. In Sweden there exist about 620 MedTech companies with at least five employees and a turnover of at least 1 million SEK. Globally, Swedish MedTech represents about 4% of the total annual turnover of the MedTech industry, which, considering Sweden is only was the 22nd largest economy in the world in 2018, is quite substantial (The World Bank, u.d.).

All medical devices produced in Sweden have to, in addition to Swedish legislation, comply with two EU-regulations that came into force in 2017 (Swedish Medical Products Agency, 2019). These two regulations are gradually replacing three older directives as they are better fitted to today's technological development. The new regulations will both be fully implemented by 2022 (European Commission, u.d.). As the EU-regulations are equal for all nations, a product complying with the regulations can be marketed in all member states (Swedish Medical Products Agency, 2015). A product that complies with the EU-regulations is still required to go through the same product approval process in Japan.

The Japanese market is one of the most important markets for Swedish MedTech industry (Business Sweden Tokyo, 2019). In addition to having a large population and a compulsory Healthcare system they also suffer the same issue as Sweden - an aging population.

3.3 Actors of relevance

A wide range of actors has been involved in the negotiations, the development and now in the implementation of the EPA. The section below serves the purpose of clarifying what role each organization plays with regards to the EPA, to the MedTech industry or a combination of both. This is however not a fully exhaustive list of all the actors involved, but a list of the actors that the authors have identified as most important with regards to Swedish MedTech companies in Japan.
3.3.1 World Trade Organization (WTO)

The World Trade Organization (WTO) are managing the global rules of world trade and are responsible for the trade to flow as smoothly, predictably and freely as possible (World Trade Organization, u.d.). In recent years the number of Regional Trade Agreements (RTAs), such as the EU-Japan EPA, has increased in number as well as in complexity (World Trade Organization, n.d.). RTAs are mutual agreements between two or more partners and since discrimination among trading partners is not allowed by the WTO, they are exemptions that are authorized under the WTO by a set of rules. For example, an RTA must cover substantially all trade.

3.3.2 Japanese Actors

Japanese Government

The two ministries that mainly are working with the EPA issues related to MedTech companies are The Ministry of Health, Labour and Welfare (MHLW) and The Ministry of Economy, Trade, and Industry (METI). Officials from these ministries act as representatives from the Japanese government in the EPA committees. See more about the EPA committees in 3.3.2.

Pharmaceuticals and Medical Devices Agency (PMDA)

PMDA is an agency that was created in 2004 in order to offload the MHLW by processing applications for pharmaceuticals and medical devices (Business Sweden Tokyo, 2019). Their obligation is to protect the public health by assuring safety, efficacy, and quality of pharmaceuticals and medical devices (PMDA, n.d.). They are also the ones that are providing relief compensation for people that have suffered from negative effects from pharmaceuticals or biological products.

3.3.2 Ventures Between the EU and Japan

EPA Committees

With the agreement coming into force, a number of committees were created. They are all included in the actual agreement and they are designated to make sure that the implementation of the EPA is carried out correctly and to drive the work forward. There is one head committee for the whole agreement, the Joint Committee, which is responsible for the work of ten specialized committees. (The European Union and Japan, 2018, pp. 536-537).

The Joint Committee is to meet once a year and it is co-chaired by one representative from the European Commission and one representative from the Japanese government. Their role is to ensure that the agreement operates properly and effectively. (The European Union and Japan, 2018, pp. 533-534)

The ten specialized committees have one chapter each in the agreement and they are responsible for the effective implementation and operation of their chapter. The content in the chapters can only be modified by the Joint Committee. There are mainly three committees that address issues related to the MedTech industry; the Committee on Trade in Goods, the Committee on Trade in Goods, the Committee on Technical Barriers to Trade and the Committee on Regulatory Cooperation. (The European Union and Japan, 2018, pp. 49-51, 169-171, 447-449)
EU-Japan Centre for Industrial Cooperation

The EU-Japan Centre for Industrial Cooperation is a joint venture between the European Commission and the Japanese Government. It was founded in 1987 with the purpose of promoting all forms of industrial trade and investment cooperation between the two economies. The head office is located in Tokyo and they also have one office in Brussels. Amongst various range of activities, they perform many different activities, including for example, training for companies, business services and activities for innovation cooperation. More information about the activities related to the work with the EPA is obtained in the empirics. (EU-Japan Centre for Industrial Cooperation, n.d.)

3.3.3 Actors of the European Union (EU)

In negotiations and implementations of FTAs, it is the European Commission, hereafter the Commission, that is responsible from the EU side. However, there is a number of other actors that have to be involved in order to reach an agreement. The Commission first need to get permission from the European Council to negotiate on behalf of the European Union. In order to coordinate the negotiating position of the EU with the member states, they consult with the council’s Trade Policy Committee. When an agreement has been drafted, after negotiations with the counterpart, it needs authorization from the Council and the European Parliament in order to sign the agreement on behalf of the EU. (European Commission, 2019)

The European Commission

The Commission is organized into different policy departments, called Directorates-General (DGs) (European Commission, n.d.). They are responsible for the development, implementation and management of EU policy, law and funding programs related to their specific policy areas. There are mainly two DGs that have been involved in the negotiation and in the work with the implementation of the EPA: The Directorate-General for Trade, hereafter DG TRADE, and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, hereafter DG GROW. DG TRADE is responsible for EU policy on trade with countries beyond the borders of the EU (European Commission, n.d.). DG GROW is responsible for EU policy on the internal market, industry, entrepreneurship and small businesses (European Commission, n.d.).

Delegation of the European Union to Japan

The offices outside of the EU are called delegations and they are managed by the European External Action Service. Their task is to promote the interests and policies of the EU. They can also be asked to deal with different forms of outreach programs. (European Commission, n.d.)

The Delegation of the European Union to Japan represents the EU in Japan and is led by the Head of Delegation. They are divided into different sections and the Trade section supported the negotiations of the EPA. They are now also working with the implementation of the agreement together with member states of the EU and companies. (Delegation of the European Union to Japan, 2018)
European Business Council in Japan (EBC)
The European Business Council (EBC) consists of 16 European National Chambers of Commerce and Business Associations in Japan (European Business Council in Japan, u.d.). They have been working to improve the trade and investment environment for European companies in Japan since 1972. They currently work for approximately 2500 different local European corporate and individual members. The EBC has 24 different industry committees and the one working with issues related to MedTech is the committee of Medical Equipment & Diagnostics. This committee works closely with the MHLW and PMDA as well as other related industry associations, with the goal to make it possible for European medical equipment to be available on the Japanese market (European Business Council in Japan, n.d.).

3.3.4 Swedish Actors

The Embassy of Sweden in Tokyo, Japan
The Embassy of Sweden represents Sweden and the Swedish government in Japan. The Embassy is part of Sweden’s missions abroad and they report directly to the Ministry for Foreign Affairs (Government Offices of Sweden, 2016). However, they are at the same time an autonomous government agency. Over the years, Sweden and Japan have developed strong partnerships in a number of areas, including amongst others; business, trade, science and innovation (Embassy of Sweden Tokyo, 2017).

Business Sweden
Business Sweden is an organization owned by the Swedish Government and the industry (Business Sweden, n.d.). Their function is to help Swedish companies increase their global sales and for international companies to invest and expand in Sweden. Business Sweden’s activities in Japan include supporting companies with, amongst other things, counseling, market analysis and contacts (Business Sweden, n.d.). Both the office in Stockholm and the office in Tokyo have been involved in the work with the EPA.

The Swedish Chamber of Commerce and Industry in Japan (SCCJ)
The Swedish Chamber of Commerce and Industry in Japan (SCCJ) has existed in Japan since 1992, with the mission to promote Sweden-related business in Japan by supporting the Swedish business community and by creating a more favorable market environment for its Swedish, Japanese and other member companies (SCCJ, n.d.). Currently, 89 companies are members of the SCCJ and the chamber itself is a member of the European Business Council in Japan (SCCJ, n.d.).

National Board of Trade Sweden
The National Board of Trade is responsible for issues related to foreign trade, the Internal Market and trade policy. It is a Swedish governmental agency and their mission, which has been assigned to them by the Government, is to promote an open and free trade with transparent rules. Amongst other services, they provide the Government with analysis and background material related to international trade negotiations, they perform long-term analyses of trade-related issues and they publish material that is intended to increase the awareness of the role of international trade. (National Board of Trade Sweden, n.d.)
3.3.5 Simplified Schematic Overview Over the Actors

To explain the rather complex pattern of how the different actors involved in the EPA and/or the MedTech industry are intertwined, the figure below has been developed. The blue boxes represent the four main actors of relevance (from a Swedish perspective). The grey ovals represent the actors that the authors have identified as important for the negotiation and/or for the implementation of the EPA. The arrows show how the actors are all connected to each other and the white boxes are examples of actors that mediate the connections. It is not a mutually exclusive and a collectively exhaustive illustration, but a simplified schematic overview.

**Figure 3: Simplified schematic overview of the actors involved in the work with the EPA (author’s).**
4. Empirics

This part includes all the empirical information that has been retrieved during the collection of data. It is divided into three different case study categories: MedTech Companies, Life Science Companies and Organizations connected to the EPA and/or the MedTech industry. In the end the different categories’ findings are compiled in matrices, one matrix per category.

4.1 MedTech Companies

4.1.1 Definitions

MedTech companies are companies within the MedTech industry that sell products that are categorized as medical devices. The definition of what is considered a medical device can vary depending on the country. Since this case study focuses on the companies’ activity on the Japanese market, companies will only be considered as MedTech companies if they sell products that are categorized as medical devices in Japan.

The different cases are divided into four parts: Background, Knowledge about the EPA, Effects from the EPA and Collaborations. Background includes general information about the company, information about their business in Japan and challenges they experience in the Japanese market. Knowledge about the EPA contains information about how much the company knows about the EPA and from where they have obtained their knowledge. Effects from the EPA goes into the effects the company has experienced or observed. Collaborations refers to if the company is part of any lobbying or industry-specific organization in Japan.

4.1.2 Company Overview

Below is a table overviewing the age, size, and details concerning the Japanese side of the business of the MedTech companies.

<table>
<thead>
<tr>
<th>Company</th>
<th>Year of foundation</th>
<th>Number of employees worldwide</th>
<th>Global revenue (in billion SEK)</th>
<th>Number of years on the Japanese market</th>
<th>Number of employees in Japan</th>
<th>Percentage of global revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elekta</td>
<td>1972</td>
<td>3800</td>
<td>14</td>
<td>23</td>
<td>150</td>
<td>8-9</td>
</tr>
<tr>
<td>Mölnlycke</td>
<td>1849</td>
<td>7000</td>
<td>16</td>
<td>15</td>
<td>50</td>
<td>&lt;11</td>
</tr>
<tr>
<td>Vitrolife</td>
<td>1994</td>
<td>400</td>
<td>1,2</td>
<td>10</td>
<td>18</td>
<td>&lt;15</td>
</tr>
</tbody>
</table>

*Table 1. Overview of the MedTech companies.*

4.1.3 Elekta

The information, in this case, was retrieved from an interview with Ken-Ichiro Araki, CFO at Elekta in Japan and Tamao Otsuka, RA Manager at Elekta in Japan. The interview took place in Elekta’s office in Tokyo on the 18th of October 2019.
**Background**

Elekta AB was founded in 1972. Their main business is focused on the treatment of tumors and their product Lexel gamma knife is their best-known product. Elekta employs about 3800 people worldwide and has a turnover of almost 14 billion SEK.

Elekta started an office in Japan in 1996, which now employs 150 people. The office is responsible for 8-9% of Elekta’s total revenue. In Japan, no manufacturing is performed. Their firsthand customers are hospitals and secondly research-organizations. They have approximately 500 hospitals as customers in Japan. Elekta sells high-end products in Japan and therefore mainly the top tier hospitals are targeted. Elekta uses distributors as the demand for service is very high and current distributors are able to provide a sufficient level of service.

The greatest challenges of establishing a presence on the Japanese market consisted of building up the organization and finding the right personnel. Additionally, MedTech regulations were vaguely described which had the effect that authorities were uncertain of how to review applications, which in turn resulted in long application processes. Eventually, this led to a situation where Japan was lagging behind with regards to MedTech products available on the market. With the creation of the PMDA, the application time was reduced. However, the toughest obstacle of operating on the Japanese market yet today, is to get new products approved. An application to PMDA takes about 6-12 months. The reason for why the Japanese government is being rather careful in this matter is that they take full responsibility for approved products, meaning that if something goes wrong with the product, government officials can be sentenced to jail or fines. Additionally, the government also tests the performance of the product as they want to make sure the new product is more efficient than the old one. A CE mark does not require performance testing. In general, the application times are getting shorter. The ultimate goal is a complete harmonization, meaning that if a product is approved in the EU, it is automatically eligible in Japan as well, and vice versa.

**Knowledge About the EPA**

There lies a problem in decoding the EPA in order to understand what it truly will mean for the business. Except for the agreement itself, information about it has been retrieved from business newspapers and from two briefings at the Swedish Embassy.

**Effects From the EPA**

The MedTech industry is not affected by tariffs, hence the EPA’s reduction of tariffs has not changed anything for Elekta. Potentially, the EPA could be used to put pressure on lobbying situations as it is a statement of a general direction of increased business between the economies.

**Collaborations**

Elekta is a member of the EBC and their committee Medical Equipment & Diagnostics. Tamao Otsuka is Elekta’s representative and attends committee meetings once a month. The committee is a channel to reach the government. The committee also meets with its Japanese and American counterparts in order to discuss what to bring up with the government. In general, the discussions are revolving deregulations. The work and influence of the committee has not changed in the most recent years.
4.1.4 Mölnlycke

The information, in this case, was retrieved from an interview with Masaru Kaneko, president at Mölnlycke in Japan. The interview took place in Mölnlycke’s office in Tokyo the 15th of October 2019.

Background
Mölnlycke is a global company, founded in 1849 with headquarters in Gothenburg. They employ approximately 7000 people worldwide and they have a yearly turnover of 180 billion yen. Their business is divided into manufacturing of single-use products for wound care and surgeries and additional services within the healthcare sector.

Mölnlycke have been present on the Japanese market for 15 years and today they are 50 people at the Japanese office. Together with the other countries within the Asia-Pacific group, they make up 11% of the company’s total business. However, the group make up 25% of the total growth of the company, of which Japan is responsible for a third. Approximately 70-80% of what they sell are classified as MedTech products in Japan. Their main customers are hospitals and due to regulations, they have to use a private distributor for the delivery and logistics of their products. Since Japan is the country with the fastest aging population, there might be big opportunities for Mölnlycke in the future.

A challenge as a MedTech company is that all new products has to be approved by the PMDA and often it requires additional assessments in Japan. However, in the last decade the launching period for new products has shortened. Before it used to be around five years, compared to today when it is only one to two years. This means that companies do not have to invest as much money as before and that the customers can get access to new products faster.

There are no major challenges related to being a Swedish company in the Japanese market since the image of Sweden is very good in Japan and because the countries are getting close in mindset.

Knowledge About the EPA
The information about the EPA has mainly been received via a monthly email from the EBC.

Effects From the EPA
No direct effects from the EPA can be identified. However, during the last five to six years the attitude of the government has changed, and they have started to listen more to the companies. This might be partly because of the EPA, which in turn has led to more harmonization and globalization.

Over the recent five to six years there has been an increase in overall competition, not only from the EU.

Collaborations
Mölnlycke are members of EBC and, within the EBC, the committee Medical Equipment & Diagnostics where they discuss common challenges. They have an open dialogue every quarter and it is always possible to send in ideas via EBC’s website. The common issues are added to a list
that is handed over to the MHLW. As part of EBC, they are officially authorized to come with input. This input might then result in a concrete action from the government, like a change in the law for example. This system has been improved over the last years.

4.1.5 Vitrolife

The information, in this case, was retrieved from an interview with Marcus Hedenskog, Rep. Director Vitrolife KK & Regional Director Japan & Pacifics. The interview took place in Vitrolife’s office in Tokyo on the 1st of October 2019.

Background

Vitrolife was founded in 1994 as one of the first companies providing IVF (In Vitro Fertilization) laboratories. The headquarter is located in Sweden and they have about 400 employees worldwide with approximately 1.2 billion SEK in turnover in 2018. Today they offer almost everything that is needed for an IVF treatment. Production is in Europe and the United States.

They have 18 employees in Japan, and they have been active on the Japanese market for 10 years. They sell all the company’s products there. Their target customers are mostly private clinics and some universities. Together with the business in Australia and New Zealand, they account for approximately 15 percent of the company’s overall business.

One challenge of being on the Japanese market is that the view on quality is different compared to Europe. For example, in Japan superficial damage to the product’s packaging reflects the quality of the whole product, whereas in Europe there is no problem as long as the product is functioning. Therefore, it can be difficult to implement changes that only the Japanese market requires. It is also more important with a long-term perspective in order to sell a product. In Europe, it is often enough with a good product and a good price, but in Japan, the buyer wants to invest in a relationship. Additionally, it can be difficult to find employees that have a set of values that is aligned to the company’s own values.

Knowledge About the EPA

Vitrolife have received information at the Swedish Embassy from SCCJ and Business Sweden at different sessions together with other companies and actors. These sessions have worked as open forums to talk about subjects related to the EPA.

Effects From the EPA

Overall, it is possible that the agreement can be considered as a symbolic gesture in order to increase the trade between the EU and Japan.

The most concrete effect on Vitrolife is that the import tariff on the products that are produced in Europe is removed. This however only applies to products produced in Europe. This has already come into force legally, but Vitrolife have to send in a collection of documents in order to prove that their products are produced in Europe. They initiated this process three months ago and they have worked together with the Japanese customs and with their importer (FedEx) to obtain knowledge about exactly what documents they need to send in. Changes in public procurement
will probably not affect Vitrolife, as they already get involved in these kinds of processes automatically.

Most of Vitrolife’s products are not accounted for as MedTech products since they are sold for use in laboratories. However, the products that are used by doctors have to go through the system for regulatory approval. It is a process that is expensive and time-consuming. It saves time if the product is already approved in Europe because then you do not have to start from scratch since you already have a lot of finished studies and data. Harmonization of technical standards, in general, would have a large impact. Common standards for electricity and the MedTech regulatory approval process would probably have the greatest impact.

There might be an increase in competition from European companies since the import cost will be lower for them compared to American and Chinese companies.

Collaborations
They do not have any direct collaboration with any committees today, but they have been looking towards EBC. Since they are still a small company and since most of their products currently are not considered as MedTech products, they do not feel any need of participating in lobbying activities on a short-term basis.

4.1.6 MedTech Companies - Compilation of Empirics
The below matrix has been developed by compiling the data from the interviews. The purpose of doing so has been to triangulate statements and to get an overview of the results. The matrix later serves the purpose as part of the foundation for the analysis, discussion and conclusion. The categories on the vertical axis has been developed with the analytical ability of the authors in combination with the interview guides.
<table>
<thead>
<tr>
<th>Challenges of being present in Japan</th>
<th>Elekta</th>
<th>Mölnlycke</th>
<th>Vitrolife</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent increase in competition.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member of EBC's Medical Equipment &amp; Diagnostics committee</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Knowledge about EPA</td>
<td>Trouble in decoding the EPA. Information gained from business newspapers and briefings at the Swedish Embassy.</td>
<td>Information from EBC.</td>
<td>Information gained from briefings at the Swedish Embassy.</td>
</tr>
<tr>
<td>Direct effects of the EPA</td>
<td>None</td>
<td>None</td>
<td>Tariffs (on non-MedTech products).</td>
</tr>
<tr>
<td>Indirect effects of the EPA</td>
<td>Potentially a better lobbying situation.</td>
<td>Attitudinal change from government.</td>
<td>None</td>
</tr>
<tr>
<td>Negative effects of the EPA</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Adjustments made to utilize EPA</td>
<td>None</td>
<td>None</td>
<td>Applications for tariff reductions.</td>
</tr>
<tr>
<td>Potential effects</td>
<td>-</td>
<td>-</td>
<td>Symbolic value, harmonization and increased competition.</td>
</tr>
</tbody>
</table>

Table 2. Overview of the empirics of the MedTech companies. The sign (-) indicates that no response has been registered.

4.2 Life Science Companies

4.2.1 Definition

Life Science in this master thesis project is defined as the combination of the industries: Pharmaceuticals, MedTech and BioTech. The two cases in this sub-chapter, does not sell products classified as MedTech on the Japanese market, and are therefore categorized as Life Science companies and not MedTech companies.

The different cases are divided into four parts: Background, Knowledge about the EPA, Effects from the EPA and Collaborations. Background includes general information about the company, information about their business in Japan and challenges they experience in the Japanese market. Knowledge about the EPA contains information about how much the company knows about the EPA and from where they have obtained their knowledge. Effects from the EPA goes into the effects the company has experienced or observed. Collaborations refers to if the company is part of any lobbying or industry-specific organization in Japan.
4.2.2 Company Overview

Below is a table overviewing the age, size, and details concerning the Japanese side of the business of the Life Science companies.

<table>
<thead>
<tr>
<th></th>
<th>Year of foundation</th>
<th>Number of employees worldwide</th>
<th>Global revenue (in million SEK)</th>
<th>Number of years on the Japanese market</th>
<th>Number of employees in Japan</th>
<th>Percentage of global revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mentice</td>
<td>1999</td>
<td>87*</td>
<td>166**</td>
<td>16</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>Pharma consulting group</td>
<td>2003</td>
<td>40</td>
<td>50</td>
<td>9</td>
<td>4</td>
<td>20–25</td>
</tr>
</tbody>
</table>

* (Mentice, 2019, p. 9)
** (Alla Bolag, 2019)

Table 3. Overview of Life Science companies. The sign (-) indicates that no response has been registered.

4.2.3 Mentice

The information, in this case, was retrieved from an interview with Daniel Sandmann, Director Global Hospital Market APAC, at Mentice. The interview took place in Mentice’s office in Tokyo on the 15th of October 2019.

Background

Mentice was founded in 1999 and has headquarters in Sweden, with additional subsidiaries in the United States, Switzerland, and Japan. They are the world leader in software and hardware solutions for endovascular simulation training.

In Japan, customers can be divided into industry clients and hospitals. The industry uses the product for training centers in their offices, as a marketing tool to sell more of its own products. Hospitals, on the other hand, use it for clinical training for their doctors. In Japan, Mentice mostly sells high-end products as well as development projects for industry clients where they customize the software. Mentice has been active on the Japanese market since 2003 and the Japanese business used to account for 15-20% of the company’s overall business. Today it accounts for around 10%.

Their product is not classified as a medical device since it does not have any direct patient contact. This might, however, change in the future when their technology has developed to the level where it can be incorporated into the clinical routine. In that case it will have to go through the more rigorous approval process as a medical device product. The greatest challenges Mentice faces today are; the high level of service requirements in Japan and the difficulty of recruiting adequate people who possess a sufficient level in English. However, English language proficiency has improved significantly over the last years.

Japan has historically had the highest prices when it comes to MedTech. The reason is the extremely service-oriented and complex supply chain structure. However, now the prices are going down and the Japanese business climate has opened up over the past five to ten years.
Knowledge About the EPA
There is no particular source from where Mentice obtains information about the EPA.

Effects From the EPA
Mentice have not experienced any effects from the EPA so far.

Collaborations
Mentice is not part of any lobbying or industry-specific organization in Japan.

4.2.4 Pharma Consulting Group
The information, in this case, was retrieved from an interview with Kai Eriksson, manager of the Japanese division of Pharma Consulting Group. The interview took place in Pharma Consulting Groups' office in Tokyo the 30th of September 2019.

Background
Pharma Consulting Group is a subsidiary of the Swedish company PCG Solutions. PCG Solutions was founded in 2003 in Uppsala, Sweden. They employ 40 people and have a revenue of 50 million SEK. The initial business model was centralized around conducting clinical trials for pharmaceutical companies. In 2004, they changed their business and started offering IT-solutions to enhance the efficiency of clinical trials.

The Japanese division was founded in 2010. At the time, one employee worked at the office, which now has grown to four people. The percentage of the total revenue from the Japanese division is about 20-25%.

Challenges of being active on the Japanese market revolve around cultural challenges, in terms of differences of how to conduct business. Also, the view of quality is different, Japanese customers have a higher demand for service. Lastly, there exists a bias towards Japanese products and a preference to work with Japanese companies rather than foreign ones.

Knowledge About the EPA
PCG Solutions have a division in Sweden, focused on clarifying laws and regulations relevant for the business. Through that division, Pharma Consulting Group in Japan received information regarding the agreement. In general terms, Pharma Consulting Group is ahead of its customers with regard to understanding the agreement.

Effects From the EPA
In Japan, there exists a similar law to GDPR called APPI. The EPA determined that these laws could be considered equivalent. This enables Pharma Consulting Group to move data more freely and to not be restricted by where servers are based geographically. It has no dramatic significance on Pharma Consulting Groups’ business, but it simplifies it to some extent.
The last two years, there has been an increase in competitors on the market. However, it is uncertain whether this depends on the EPA or the development in the Japanese market, where customers to a bigger extent request the type of IT-service Pharma Consulting Group offers.

Pharma consulting group has not made any direct changes in order to utilize the agreement.

Collaborations
Pharma Consulting Group is not part of any lobbying or industry-specific organization in Japan.

4.2.5 Life Science Companies - Compilation of Empirics
The below matrix has been developed by compiling the data from the interviews. The purpose of doing so has been to get an overview of the results. The matrix later serves the purpose as part of the foundation for the analysis, discussion and conclusion. The categories on the vertical axis has been developed with the analytical ability of the authors in combination with the interview guides.

<table>
<thead>
<tr>
<th></th>
<th>Mentice</th>
<th>Pharma Consulting Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challenges of being present in Japan</td>
<td>High service level, recruiting adequate people.</td>
<td>Cultural differences, high demand for quality and service level, bias towards Japanese products/companies, a recent increase in competition.</td>
</tr>
<tr>
<td>Members of EBC committee</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Knowledge about EPA</td>
<td>-</td>
<td>Division in Sweden informing about the EPA.</td>
</tr>
<tr>
<td>Direct effects of the EPA</td>
<td>None</td>
<td>Harmonization of GDPR and APPI.</td>
</tr>
<tr>
<td>Indirect effects of the EPA</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Negative effects of the EPA</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Adjustments made to utilize EPA</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Potential effects</td>
<td>-</td>
<td>Harmonization of the pharmaceutical approval process could change business.</td>
</tr>
</tbody>
</table>

Table 4. Overview of the empirics of Life Science companies. The sign (-) indicates that no response has been registered.

4.3 Organizations Connected to the EPA and/or the MedTech Industry

The organizations interviewed all play different roles with regards to EPA and have different areas of expertise, which resulted in a wide variety of information retrieved.
4.3.1 Definitions

The different cases are divided into two parts: **Background** and **Effects from the EPA**. Background includes general information about the organization and how they have been involved in the work with the EPA. Effects from the EPA cover the effects the organization has identified.

4.3.2 Swedish Embassy in Tokyo, Japan

*The information, in this case, was retrieved from an interview with Johannes Andreasson, First Secretary at the Embassy of Sweden in Tokyo, Japan. The interview took place at the Swedish Embassy on the 2nd of October 2019.*

**Background**

The Swedish Embassy in Tokyo represents Sweden and the Swedish government in Japan. Sweden and Japan collaborate on a number of areas, such as science, innovation, creative industries and education. The Embassy help Swedish companies with issues they might have on the Japanese market. In business-related matters they work closely with SCCJ and Business Sweden.

In order to inform the Swedish companies about the EPA they have sent out information and they have also organized sessions with experts from the National Board of Trade Sweden, Business Sweden’s Stockholm office, the Delegation of the European Union to Japan and the EU-Japan Center for Industrial Cooperation. In these sessions, they went through the agreement and the necessary actions in order to utilize it. They have also had individual meetings regarding the trade agreement with some of the companies. Usually, they meet with big companies that have people assigned to these specific matters, and therefore they already have good insight into the agreement. However, there is a difficulty reaching the smaller companies that have less insight into the agreement and that might benefit from it the most. They put the information related to trade barriers they receive from these kinds of meetings together and forward it to the Delegation of the European Union to Japan. Business Sweden, National Board of Trade Sweden and the chambers of commerce have also been around in Sweden to spread the knowledge about the EPA. The Embassy has together with Business Sweden in Tokyo, SCCJ, National Board of Trade Sweden, Business Sweden in Stockholm and the Ministry for Foreign Affairs created an EPA network. Within this network they share information via email, video conferences, and physical meetings. It is a way of keeping track of what is going on, with the purpose of driving the work forward.

There are many actors that are working continuously with the agreement. The system that has been created for the implementation consists of ten committees that meet once a year. The committees consist of representatives from the European Commission and the Japanese government and correspond to the different articles in the agreement. They meet every second year in Japan and every second year in Europe. Sweden send their input on what they want to be discussed on these meeting to Brussels.

**Effects From the EPA**

For Sweden, the greatest direct effects from the EPA are lower import tariffs on agricultural and wood products. The greatest potential in general effects will be regarding the harmonization of regulations and standards.
In parallel with the agreement, a list of NTMs was created. Japan promised to solve these and the majority of them were solved during the time they were negotiating over the agreement, but some remain, and some others have been added. The Embassy is still working with this together with the Delegation of the European Union to Japan and other member states.

The Embassy believes that now with the agreement as a foundation, there is room to reach closer cooperation when it comes to regulations and standards. Since it is written in the EPA that harmonization and cooperation are encouraged, the trade barriers will be dealt with faster. However, it is also up to the companies to drive this change forward.

4.3.3 Business Sweden

The information, in this case, was retrieved from an interview with Magnus Blondell, consultant working mainly within the life science industry at Business Sweden. The interview took place in Business Sweden’s office in Tokyo on the 2nd of October 2019.

Background

Business Sweden is a half publicly- half privately owned organization founded in 2013. Their main business is to provide consultancy services for small to medium-sized companies who aspire to grow internationally. Business Sweden has offices in 57 countries around the world.

Effects From the EPA

The effect from the EPA will not be of drastic character but will become visible within the coming 10-15 years. Data on exports to Japan will be available in one to two years, until then it will be hard to draw conclusions of the impact of the EPA. Generally speaking, product registration is a more important threshold for the MedTech industry to launch new products in Japan than import duties. Approval of medical devices is conducted by the PMDA, which classifies each product on a one to four scale, depending on their level of risk. Class one is the lowest level of risk, and basically gets approved the same day as the application is sent in. Class two to four generally takes about one to two years to get approval. Due to the EPA, the process for product approvals is more frequently discussed and there is now hope that EPA will lead to increased harmonization of requirements for product registration in Japan and EU.

EPA is not likely to have an impact on public procurement in the MedTech industry, as MedTech products, in general, are not bought through public procurement.

Swedish products have a good reputation in Japan, and it is not likely that EPA will affect that image in any way, positively or negatively.

4.3.4 European Business Council in Japan (EBC)

The information, in this case, was retrieved from an interview with Björn Kongstad, policy director at European Business Council (EBC). The interview took place in EBC’s office in Tokyo on the 18th of September 2019.
Background
EBC in Japan was founded in 1972 as a result of the growing trade between the EU and Japan. The organization strives to make business easier to conduct in Japan through policymaking and through lobbying activities.

Discussions of a trade agreement between the EU and Japan were partly initiated due to the EBC. Before the EPA it did not exist a mechanism for negotiations between the economies. When the idea of the EPA was launched initially, it faced great resistance from the automotive industry. This attitude changed when the EU entered a trade agreement with South Korea, as the Japanese automotive industry wanted to be able to compete on equal terms. After 18 official rounds of negotiations, the EPA was agreed upon.

EBC mainly focuses on implementing parts of the agreement and following up on the effects. It is the only organization in Japan working directly with the EPA with regards to the MedTech industry.

Effects From the EPA
The agreement in general aims to ease trade between the economies through agreeing upon laws and regulations. In the agreement, there is little written about MedTech in specific. Customs and public procurement will most likely not have any significant effect on the MedTech industry, since it is an industry for which the product approval process is the greatest obstacle.

In the process of shaping the EPA, the Japanese Pharmaceutical Affairs Law was replaced by the PMDL. The new law clarified details revolving the product approval process and resulted in a shorter processing time of product approval applications.

With the creation of the EPA, two committees were created; the Committee on Technical Barriers to Trade and the Committee on Regulatory Cooperation. Their purpose is to discuss and negotiate issues regarding technical standards, deregulations, and harmonizations. However, as the committees were just recently formed, it is not certain to which extent they will affect the MedTech industry.

EBC’s committee Medical Equipment & Diagnostics has experienced a momentum since the discussion of EPA was initiated. It is uncertain whether it is a direct cause of the EPA or not, but it seems like their voice is now listened to more.

4.3.5 Delegation of the European Union to Japan

The information, in this case, was retrieved from an interview at the Delegation of the European Union to Japan. The interview took place at the office for the Delegation of the European Union to Japan in Tokyo on the 9th of October 2019.

Background
The Delegation of the European Union to Japan represents EU in Japan and aims to strengthen cooperation, promote the interests of the EU and represent EU values abroad. As with every
Free Trade Agreement that the European Commission negotiates, via DG TRADE, the European Council gave initial mandate to the Commission to start negotiations with Japan. The Commission/DG TRADE has an obligation to report back to the Member States and the European Parliament on a regular basis, via the established channels in the headquarters. The Member States were informed at the local (Japanese) level as well, particularly on the occasion of the Chief Negotiator's missions to Tokyo, where he would debrief the Member States at the end of almost every round. The European Parliament needs to be kept in the loop because they have the final voting on the agreement. In the implementation phase both the Commission and the delegation ensure the agreement is properly implemented - making sure that the text of the agreement is respected, that there is no misunderstanding on the application of the text and that non-tariff barriers (NTBs) are properly addressed.

**Effects From the EPA**

In general, the EPA is expected to have a positive effect on trade between the EU and Japan. In some sectors, like dairy and wines, it is already visible. It is however too early to measure the impact, as at least a year should be completed in order to draw some meaningful conclusions, also on the utilization rate of the agreement.

In the EPA, the MedTech sector, as other industrial sectors, is addressed through the chapters *Trade in Goods*, *Technical Barriers to Trade* and *Regulatory Cooperation*. As the general purpose of the EPA is to enhance trade between the economies by the reduction of tariffs and the establishment of increased regulatory cooperation, the EPA is expected to have positive effects in this sector as well.

During the negotiations of the EPA, the parties considered it important to, in parallel, tackle several existing NTBs, in order to make the implementation of the EPA more effective once it would enter into force. An example of an NTB being solved partly due to the negotiations of the EPA is the replacement of the Pharmaceuticals Affairs Law with the Medical Devices Act in 2014.

**4.3.6 EU-Japan Centre for Industrial Cooperation**

*The information, in this case, was retrieved from an interview with Philippe de Taxis du Poët, Minister Counsellor & General Co-Manager of the EU-Japan Centre for Industrial Cooperation. The interview took place at the office of the EU-Japan Centre for Industrial Cooperation in Tokyo on the 7th of November 2019.*

**Background**

The EU-Japan Centre for Industrial Cooperation, hereafter referred to as the EU-Japan Centre, is a joint initiative between the European Commission and the Japanese government. More specifically it is DG GROW from the commission’s side and METI from the Japanese government’s side. It was launched in 1987 and it is funded and managed from both sides. They have one office in Tokyo and one in Brussels. In total, they are 40 people with 25 people in Tokyo and 15 people in Brussels.

The EU-Japan Centre promotes cooperation between Europe and Japan, in terms of industry, trade, innovation, investment, and people mobility. Today one of their key priorities is to make
sure that the businesses in Europe know about the EPA, know how to use the agreement, and know-how to benefit from it. The companies’ knowledge, SME’s in particular, about the EPA is in general not sufficient and varies depending on country and sector. In general, the large companies have good insight into the agreement because they have the people and the money necessary in order to follow it carefully. It is harder for SMEs that might not even know that there is an agreement in place. In order to disseminate information regarding the EPA, they have set up an EPA helpdesk. The activities of the helpdesk can be divided into three main categories:

- To explain, in a very simplified way, the most important elements of the EPA.
- To guide the companies on what they should do in order to benefit from the agreement.
- To maintain a dialogue with the companies, where they answer questions and clarify uncertainties. They do this regularly via webinars, which also function as an opportunity for them to listen to the need of the SMEs.

The EU-Japan Centre also reaches out to companies proactively in order to disseminate the information. They do this in particular via their Pan-European networks. These consist of, amongst others, the Enterprise Europe Network (a network with 600 members over Europe), networks of clusters, networks of regions and networks of research and innovation projects. When they simplify the agreement, to make it easier to understand, it is important to balance it whilst still providing solid and correct information. The risk is an oversimplification, which might mislead people. This is why everything they do, all their documents and guides, are first validated by the European Commission.

Another important thing the EU-Japan Centre does is to regularly organize cluster and business missions. On these missions, a group of companies and clusters come from Europe to meet potential partners in Japan. The EU-Japan Centre do this in close cooperation with the organizations of the member states, in particular, the Trade promotion organizations (for example Business Sweden). There are mainly two things the companies have to be prepared for when looking for business opportunities in Japan: First, that it will take a long time to make a deal and second, that before talking about business, you have to build a personal relation in order to establish trust.

**Effects From the EPA**

A common misunderstanding is that the companies will benefit from the agreement automatically. In order to benefit from the agreement, the companies have to complete certain procedures. For example, regarding rules of origin.

One of the important aspects of the EPA is mutual commitments with regard to government procurement. Both sides have agreed to further open government contracts to each other’s businesses, both in terms of the number of government entities and sectors covered and by streamlining procedures. These commitments are on top of already existing ones regulated by the World Trade Organization’s Agreement on Government Procurement (GPA).

On a global level, the multiplication of FTAs is a challenge for SMEs as they cannot spend the time necessary to learn how to benefit from them one by one. This sometimes leads to underutilization of the full potential of FTAs.
The EPA is a big important element, but it is not enough just by itself. Another aspect of how the EU-Japan Centre works with the agreement is that they integrate these EPA-related services into other services which are also necessary for European SMEs to export to Japan. Examples of these other services are a helpdesk for public procurement, a helpdesk for technology transfer and a helpdesk for clusters and regions in Europe.

EPA is the result of a long process, including a number of dialogues. It is important to maintain these dialogues since there are new technologies that require inventions of new design norms and regulatory standards. If the dialogue is not maintained it is very easy to diverge and therefore it is very important for the EU and Japan to keep close to each other in these fast-emerging technology sectors.

Implementing the EPA was a big effort and now the focus is on integrating the EPA into the other elements as mentioned above. However, in the future there might be an even more important effect: How the EPA can trigger something new, which is not strictly mentioned in the agreement. Since the agreement reinforces the connection between EU and Japan, it creates momentum and a good mindset on both sides, which might open doors to something new. Two potential examples of this:

- In terms of sectors, the EU-Japan Centre can see that businesses are increasingly interested in cooperation in the digital economy and circular economy, and even considering cooperation in the defense sector, which is new. It is a result of this new mindset, that has been created by the EPA, and also of the geopolitical situation in the world.
- An increased cooperation between EU and Japanese companies in the area of entering new markets. Today it is already a big trend that EU-companies team up with Japanese companies in order to enter new markets together. By teaming up, companies can benefit from each other’s technologies and knowledge about markets of interest. About 70% of the German companies in Japan are currently cooperating with Japanese companies in this sense.

An aspect that is indirectly connected to the EPA is that it will intensify the bilateral cooperation between the EU and Japan. Because if we look at the world today, the EU and Japan are globally on the same line by defending multilateralism, fighting unilateralism, fighting for open rules-based trade and being together in the Paris Agreement regarding climate change. It creates a good environment to further enhance their bilateral cooperation and also for the EU and Japan to further operate on the global scene.

4.3.7 Organizations Connected to the EPA and/or the MedTech Industry - Compilation of Empirics

The below matrix has been developed by compiling the data from the interviews. The purpose of doing so has been to triangulate the data and to get an overview of the results. The matrix later serves the purpose as part of the foundation for the analysis, discussion and conclusion. The categories on the vertical axis has been developed with the analytical ability of the authors in combination with the interview guides.
<table>
<thead>
<tr>
<th></th>
<th>Business Sweden</th>
<th>EBC</th>
<th>Embassy of Sweden</th>
<th>Delegation of the European Union to Japan</th>
<th>Centre for Industrial Cooperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General direct effects of EPA</td>
<td>*</td>
<td>-</td>
<td>Tariff reductions.</td>
<td>Positive effect on trade.</td>
<td>Public procurement</td>
</tr>
<tr>
<td>General indirect effects of EPA</td>
<td>-</td>
<td>-</td>
<td>Solving a list of NTMs.</td>
<td>-</td>
<td>Momentum and changed mindset.</td>
</tr>
<tr>
<td>EPA direct effects on MedTech</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>EPA indirect effects on MedTech</td>
<td>Product approval process (harmonization and discussion).</td>
<td>Product approval process. PMDL. Increased potential for Medical Equipment &amp; Diagnostics committee.</td>
<td>-</td>
<td>PMDL</td>
<td>-</td>
</tr>
<tr>
<td>Potential general effects of EPA</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>How it can trigger something new. Increased bilateral cooperation on the global arena.</td>
</tr>
<tr>
<td>Potential effects on MedTech of EPA</td>
<td>-</td>
<td>Deregulations and harmonization of technical standards.</td>
<td>Harmonization of regulations and standards. Room for closer cooperation.</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 5. Overview of the empirics of the Organizations connected to the EPA and/or the MedTech industry. The sign (-) indicates that no response has been registered.
5. Analysis

This part includes the analysis of the information obtained in the empirics. First, a cross-case analysis is performed on each of the three different case study categories individually. Then a cross-cross case analysis is made between the different cross-case analyzes. All statements and citations from companies and organizations in this chapter are retrieved from the Empirics chapter.

5.1 Cross Case Analysis

5.1.1 MedTech Companies

Concerning the challenges of being present on the Japanese market, all companies identified the product approval process as one. Additionally, Mölnlycke has experienced a recent increase in competition and Vitrolife has found it challenging to meet the higher demand for quality, recruiting the right people and building trust and relationships with customers.

Both Elekta and Mölnlycke are members of EBC’s Medical Equipment & Diagnostics Committee. Vitrolife is currently not a member, as most of their products are not classified as MedTech.

Elekta and Vitrolife have both obtained information regarding the EPA from the briefings at the Swedish Embassy, whereas Mölnlycke has obtained their information from EBC. Elekta has also received information from business newspapers and the agreement itself, they have however experienced difficulties in decoding the agreement.

As for effects due to the EPA, no direct effects except for the tariff reduction of Vitrolife’s non-MedTech products identified in the empirics. Regarding indirect effects, Mölnlycke are experiencing that the attitude of the Japanese government has changed in a positive direction the last five to six years and that they are now more eager to listen. Elekta says that no indirect effects have been experienced but that EPA potentially could be used as leverage in lobbying situations in the future. Vitrolife states that the agreement has a symbolic value in the sense of a general direction of increased trade between the economies. Vitrolife also states that competition might increase in the future on their non-MedTech assortment due to the tariff reductions.

5.1.2 Life Science Companies

Both Mentice and Pharma Consulting Group consider the expected service level in Japan as a challenge. Moreover, Mentice mentions that it is difficult to recruit people with the required level of English. Pharma Consulting Group mentions that there are differences in the way of conducting business and that there exists a bias towards Japanese companies.

Mentice and Pharma Consulting Group are not members of any lobbying or industry-specific organization in Japan. Pharma Consulting Group are well informed about the EPA thanks to their special division in Sweden. Mentice, on the other hand, does not have an established funnel for this type of information.
The only effect Pharma Consulting Group has noticed from the EPA so far is the harmonization between GDPR and APPL. Mentice has not experienced any effects. Neither Mentice nor Pharma Consulting Group has made any adjustments in order to utilize the EPA.

5.1.3 Organizations Connected to the EPA

The three direct effects identified in the empirics are tariff reductions, public procurement and a generally positive effect on trade. The EU-Japan Centre also states that EPA has created momentum and a good mindset from both sides which potentially might trigger additional cooperation between European and Japanese companies on new markets and new sectors. The Delegation of the European Union to Japan states that EPA is expected to have a positive effect on trade in general. The Embassy of Sweden states that the negotiations of the agreement enabled the EU and Japan to agree upon several NTMs that reduced barriers to trade.

Revolving EPA's significance for the MedTech industry, both EBC and the Embassy of Sweden talked about harmonization of regulations and technical standards as a potential future effect. EBC and Business Sweden specifically mentioned the increase of discussions regarding harmonization of the product approval process. The EBC also mentioned that the replacement of the Pharmaceutical Affairs Law with the PMDL is an important factor, leading to a decreased processing time for product approvals and that the Medical Equipment & Diagnostics committee might have advanced their bargaining/negotiation position. In addition, the Embassy of Sweden said that the agreement might give room for closer cooperation between the economies in the future.

One challenge that is stated by the Swedish Embassy, as well as the EU-Japan Centre, is that it is difficult to reach smaller companies with information about the EPA. The EU-Japan Centre can see this based on the level of knowledge the companies have about the EPA and the two organizations both state that the reason is mainly due to the limited resources of the smaller companies.

5.2 Cross-cross Case Analysis

Four types of challenges are mentioned by the companies concerning business in Japan: Time consuming product approval process, high demand for quality/service, recruiting the right people and the bias from Japanese customers towards Japanese companies. With regard to these challenges, no significant difference has been registered by any of the MedTech companies after the EPA came into force. However, information has been retrieved that is pointing towards a potential positive attitude change from the government, a symbolic value of increased trade between the two economies and a potentially better environment for lobbying.

According to Magnus Blondell at Business Sweden, the product approval process is the biggest challenge for conducting business in Japan for the MedTech industry, a fact that is supported by the MedTech companies interviewed. The EPA does not target this process in specific. There is however evidence supporting that the EPA already has had an indirect effect on the process, that it is currently affecting it and that it could have a long-term effect in the future:
• The law on pharmaceuticals and medical devices was divided into two separate laws. The law, that had previously been hard to interpret for authorities and companies, became easier to understand and resulted in shorter processing time for product approvals.

• Several sub-cases claim that there has been a change in attitude of the government and EBC stated that their committee on Medical Devices & Diagnostics has gained momentum. It is, however, hard to tell how much impact this attitudinal change and momentum has had and will have.

• As part of the EPA, the Committee on Regulatory Cooperation, was created. The purpose of the committee is to work for a closer regulatory cooperation between the economies. Since the product approval issue is of regulatory character, it is likely that this committee will be able to affect it in the future.

It is clear that the MedTech companies have not made any major changes in order to utilize EPA or gain knowledge about it. Mölnlycke, Elekta, and Vitrolife have all acquired knowledge enough to know that EPA does not have any direct effects on their MedTech products. They are however unaware of indirect effects from the negotiations, such as the PMDL. Neither of them mentioned the Committee on Regulatory Cooperation during the interviews, which indicates that they either lack knowledge about it or that it has not yet affected the MedTech industry.

Vitrolife and the EU-Japan Centre, both mention the importance of investing a lot of effort in personal relations with the Japanese counterpart in order to conduct business in Japan. In order to establish a partnership or to sell a product it is important to have a long-term perspective and to enforce trust.
6. Discussion

The MedTech companies experience a few different challenges of conducting business in the Japanese market. What they all state, is that the product approval process for medical devices as a challenge. Looking at the empirics, none of the MedTech companies have experienced any direct positive or negative effects since the EPA was put into power.

In the sub-case studies of Organizations connected to the EPA and/or the MedTech industry, empirics indicates that the EPA has had a positive indirect effect on the MedTech industry. The greatest indirect effect is likely the replacement of the Pharmaceutical Affairs Law with the PMDL, which reduced the time, complexity and cost of the product approval processes. It is however not certain whether the law was replaced only due to the EPA being negotiated, or if the EPA only helped speeding up the process of replacing the law. What could be understood from the interview with the European Delegation to Japan is that many NTMs were resolved while the negotiations were ongoing and that the development of the PMDL was one of them. The reason why the companies are not aware of this is likely because it is an indirect effect, not explicitly stated in the EPA.

From several interviews, there is a somewhat unanimous perception that the Japanese government has changed its attitude towards reducing trade barriers in general and has become more open to listen and to solve trade obstacles. It is difficult to establish exactly when this change commenced, and it is, therefore, hard to tell whether it is a direct effect of the EPA or if the reason behind it is a changed view on international trade in general. Nevertheless, as the MedTech industry faces regulatory issues, that could be solved through lobbying activities, the attitudinal change is positive.

Looking at future effects, it is hard to tell how much impact the EPA will have on the MedTech sector. As the biggest obstacle for the MedTech industry is the product approval process, the ideal scenario would be a complete harmonization. This would mean that if a product is approved in the EU, it is automatically approved to be put on market in Japan and vice versa. This future scenario, however, seems to be rather distant. One of the key factors behind this appears to be that the Japanese government take on a bigger portion of responsibility for approving medical devices than in the EU. Japanese politicians that are involved in an approval process are legally responsible for the safety of that product. In general, however, the attitudinal change of the government, the possibly gained momentum of the lobbying situation for the Medical Device & Diagnostics committee as well as the creation of the two new EPA committees dealing with regulatory cooperation and technical standards, opens up for a more harmonized product approval process in the future.

Based on the empirics, it is too soon to judge whether the competition has increased or not. Mölnlycke states that the competition has increased in general over the recent years and Vitrolife states that it is possible that the competition from European companies will increase due to the EPA. The fact that long business relations are highly important for doing business in Japan, barriers to entry can be considered quite high. The MedTech companies in the case study have all been active on the Japanese market for several years and therefore have the advantage of already
established relations, compared to new entrants. They are likely facing a bright future with the potentially positive effects from the EPA and additionally a quickly aging Japanese population. The aging population will lead to a higher demand for medical care and hence for medical devices. Something that will make it easier for existing companies to operate on the Japanese market is the increased level of English. Mentice states that the level of English has increased over the recent years and non-market access issues should not be underestimated. This also makes it a more attractive market for potential entrants.

In order to increase utilization of the new agreement, it is important that the companies drive the development forward, for example by reporting trade barriers to organizations like Business Sweden and the EBC. By doing so, MedTech companies might be able to enforce a great impact even though the two greatest effects, public procurement, and tariff removal, does not really affect them. In order to make this happen, it is critical to make sure that they understand why it will be beneficial for them. That is why the actors working with the implementation of the EPA have to put a lot of effort into spreading the information about the EPA and to make it comprehensible for the companies. This is considered a challenge when it comes to SMEs as mentioned by the Swedish Embassy as well as the EU-Japan Centre. Nevertheless, this is extra important in the MedTech industry since it is an industry with a high degree of SME participation. The SMEs might also be the ones that would benefit the most since they do not have the resources required to overcome costly and time-consuming trade barriers.

According to the EU-Japan Centre, it is common for EU companies to partner up with Japanese companies, in order to enter new markets. The EPA aims to integrate the economies further, which is likely to lead to more cooperations like these. Potentially, this could mean an increase in partnerships for the Swedish MedTech sector as well, making Japan an even more important gateway for Swedish MedTech companies into other markets in Asia.
7. Conclusions

7.1 Summary of Conclusions

The objective (see 1.4.1) of this master thesis project is to answer the research questions regarding the effects of the EPA on Swedish MedTech companies established in Japan and potential entrants, as well as future effects on the industry. Through extensive data collection and analysis, the authors can conclude that two of the greatest direct effects of the agreement, public procurement and tariff reduction, will not affect the MedTech industry. The reasons behind it are the low degree of public procurement in Japan for medical devices and the fact that tariffs were low for medical devices already before the agreement.

The EPA does not explicitly mention the MedTech industry, but indirectly addresses it through the chapters *Trade in Goods, Technical Barriers to Trade* and *Regulatory Cooperation*. Hence the effects of the EPA for the MedTech industry will be indirect.

The authors have identified the product approval process as the greatest obstacle for foreign MedTech companies conducting business in Japan. The process is both time-consuming and costly and a product approved in the EU still has to be approved by the Japanese PMDA. The analysis of the empirics indicates that the EPA already has had an effect on this process and will continue to affect it in the future. According to EBC and the Delegation of the European Union to Japan, the EPA played a role in the negotiations behind the PMDL in 2014, which in turn resulted in a less costly, less complex and less time-consuming processing time for product approvals. Additionally, the empirics indicate a recent attitudinal change from the government, including a greater will to listen to industry-specific problems and a will to solve trade thresholds. It is however uncertain whether this is a direct cause of the EPA or if it is a combination of other factors. A final factor that points towards the EPA being able to affect the product approval process in the future, is the now existing committee on Regulatory Cooperation. One of its purposes is to drive harmonization forward with help from other actors like, for example, the Swedish EPA network.

It is difficult to judge whether the competition has increased due to the EPA or not. However, the future look bright for the Swedish MedTech companies since they have established relations over a long time on the Japanese market, the market for medical devices is expected to grow due to the aging population and the increasing level of English.

In order to reach a high rate of utilization of the EPA it is important that the actors responsible, manage to disseminate information and educate companies about the agreement. One important issue is that it is difficult to reach the smaller companies, especially since the MedTech industry has a high level of SMEs.
7.2 Answering the Research Questions

1. What are the current effects of the EU-Japan EPA on Swedish MedTech companies in Japan?
   a. What are the positive effects?
   No direct effects have been registered in any of the data collection. The main points of impact of the EPA revolve around public procurement and tariff reductions, which are areas that have little to no impact on the MedTech industry. However, in the process of developing the EPA, the Pharmaceutical Affairs Law was replaced by the PMDL. This resulted in a shorter and less costly approval process for medical devices. Whether the PMDL is a direct effect of the EPA or if it would have happened anyway is difficult to determine, but the data collected indicates that there is a connection.

   During the data collection, information revealing an attitudinal change from the Japanese government has been retrieved. It now seems like there exists a greater will to listen to the MedTech companies and to cooperate in order to reduce thresholds to trade. It can however not be determined whether this is an effect of the EPA or if it is an effect of other factors. All effects (negative) from Japanese companies on EU/Sweden market(s) are not included in this study (see delimitations & empirics).

   b. What are the negative effects?
   The authors have not identified any data that indicates that the EPA has had any negative effects. One company stated that competition had increased over the past years, but as the competition were not only EU-companies, it cannot be determined whether this is an effect of the EPA or not.

   All negative effects from Japanese companies on the EU market are not included in this study (see sub-chapter 1.3 Delimitations).

   c. Efforts to utilize the agreement?
   No data indicates that any of the MedTech companies have made any major efforts in order to utilize the agreement. An explanation to this is that no changes in the agreement directly affect the industry, such as tariff reductions or public procurement.

   The efforts made have been to attend information meetings regarding the agreement and to some extent make sense of the actual document.

2. What future effects may EPA have on Swedish MedTech companies in Japan?
   a. For companies already established on the market
   From empirics, it has become clear that the biggest challenge for the industry in Japan is the time consuming, complex and costly product approval process. There are factors that indicate that the EPA might be able to change the situation to some extent. With the implementation of the EPA, the Committee on Regulatory Cooperation was created. One of the missions of the committee is to work on harmonization issues. The level of impact they will have on the product approval process is however hard to determine. Additionally, the attitudinal change of the government mentioned in 1a. is likely to be helpful in future lobbying situations for the MedTech industry.
b. For potential entrants
If a MedTech company, previous to the implementation of the EPA has not been successful in conducting business in Japan, it is hard to see a changed outcome now, after the implementation. The reason is the low direct impact of the EPA on the MedTech industry. The scenario in which the EPA could increase the attractiveness of the Japanese market for new entrants is by a more harmonized product approval process. If, how and when this could happen is however not clear.

7.2.1 Summary of Answers to Research Questions
No direct effect of the EPA on Swedish MedTech companies has been identified. PMDL has had an impact on the product approval process, which is identified as the greatest obstacle for foreign MedTech in Japan in general, it is, however, uncertain to which extent the EPA affected the creation of the PMDL. Empirics indicate a recent positive attitudinal change from the government but again it is uncertain to which extent the EPA has influenced the Japanese government. No negative effects have been identified, except for one company that has experienced an increase in competition over recent years. It is however not likely that the EPA is the cause of this increase. No major efforts to utilize the agreement has been made, except attending information meetings concerning the EPA. As a part of the EPA, the Committee on Regulatory cooperation was created. The committee could potentially help in further harmonization of the product approval process. A more harmonized product approval process would improve business opportunities for both established Swedish MedTech companies and for potential entrants.

7.3 Fulfillment of Purpose
The purpose of the project was to examine the potential effects of the EPA on the Swedish MedTech industry in Japan. The strategy of the research was changed in an early stage of the data collection phase, as the authors narrowed down the scope from investigating the Life Science industry to focusing Swedish MedTech companies. The interviews already booked with companies not defined as MedTech companies but within Life Science, were kept as they were considered valuable for the research. Organizations connected to the EPA and/or the MedTech industry were also interviewed. As a result of the broad selection of cases, a wide range of data and perspectives were collected, enabling the authors to advance on their quest to answer the research questions. The authors managed to accomplish this even though the agreement was put into power only seven months before the interviews took place and it was difficult to find the people with the right expertise.

7.4 Critical Review
The conclusions in this master thesis project are based on the ten interviews performed. Out of these ten interviews, three were performed with Swedish MedTech companies. This number of interviews is considered by the authors to be too scarce to draw general conclusions about whether the knowledge of the EPA and the adjustments made to utilize the EPA is equal throughout all Swedish MedTech companies in Japan. In general, more interviews would have
increased the trustworthiness of the conclusions. What limited the authors on their strife to include more interviews was the difficulty of directly contacting companies and organizations in Japan as a student. The authors therefore had to go via SSCJ and Business Sweden to get in contact with companies and organizations. This also contributed to the fact that the interviews performed were so EU-centred. The authors made unsuccessful attempts to get in contact with Japanese organizations, amongst others PMDL, which could potentially have given interesting perspectives.

The EPA is still a new free trade agreement and the literature regarding the effects of it is still rather scarce. The authors found it greatly challenging to find literature revolving the MedTech sector, which led to them learning almost everything regarding the subject during the interviews. There is always a risk in running into biased information during interviews, especially in this case, where almost only EU organizations participated in the case studies. To ensure the reliability of the results, the risk was mitigated by being transparent in the summary of interviews and through conducting interviews with companies and organizations with different perspectives. Another risk is that the data collected is incorrect as a cause of the person interviewed being misinformed or simply as a cause of a misunderstanding between the interviewer and the interviewee. This risk has been mitigated by recording each interview, by trying to confirm data collected in one interview with the interviewee in the next interview, and through having the interviewee confirming the material of the interview before publishing.

7.5 Further Reflections

The chosen methodology was an abductive approach collecting qualitative data through unstructured/semi-structured interviews. The reason for using an abductive approach was to be able to develop theory simultaneously as the data was collected, a strategy that turned out to suit the project well as theory regarding the EPA’s impact on MedTech was scarce. Qualitative data was chosen since it is still too early to extract quantitative data for calculations. As the research area was complex and the likelihood of interviewing people with highly specific knowledge of EPA was considered low, the authors did not want to conduct structured interviews. Instead, to maximize learnings from each interview, semi-structured interviews were chosen, enabling the authors to dig into the area of expertise of each interviewee.

The initial plan was to examine the potential effects of the EPA on Life Science companies but early on the authors chose to narrow down the scope to examining the potential effects on Swedish MedTech companies. The interviews already booked, that were not Swedish MedTech but Life Science companies, were not discarded as they were considered valuable for the research. To understand the EPA better and to get more perspectives on potential effects, Organizations connected to the EPA and/or the MedTech industry were interviewed as well. The broadened scope enabled the authors to collect a wide range of data, giving nuances to the research questions. The trade-off with the broad data set was however the difficulties it led to in structuring the analysis.
7.6 Suggestions for Further Research

Further research in the area of the changed attitude of the government would be of value. To investigate this, interviews with Japanese actors should be conducted. The authors tried to get an interview with the PMDA but were rejected. Should such an interview take place, it would be easier to establish whether an attitudinal change really has taken place and whether or not the EPA has had anything to do with it.

To further identify the effects of the EPA on the MedTech industry, data analysis on the export from Swedish MedTech companies to Japan should be conducted. To avoid cyclic or other external effects on the data, several years of historical trade data should be used and therefore, the analysis should wait a few years in order to have access to enough data. To support this argument, the recent attitudinal change most likely has happened faster than changes in turnover data and the effects from it have not yet become visible in financial figures.

It is still uncertain to what extent the EPA affected the replacement of the Pharmaceutical Affairs Law with the PMDL in 2014. As the PMDL has had a great impact, it would certainly be interesting to interview Japanese decision-makers in order to determine the EPA’s relevance.

As the biggest challenge of the Swedish MedTech companies is the product approval process, it would be of interest to investigate how the global harmonization negotiations are developing.

In order to investigate the future effects of the EPA further, a possible method would be to look into similar FTAs and see how they have affected the MedTech industry. It is likely that this research would be difficult to draw general conclusions from for the Swedish MedTech industry due to the high level of uniqueness of FTAs, in addition to the uniqueness of the obstacles Swedish MedTech industry faces in the Japanese market.

In order to delve further into the effects of the EPA for the Swedish MedTech companies that yet have not entered the Japanese market, it would be interesting to conduct a new case study, which only focuses on these companies. From this study it would be possible to understand what the companies consider as the biggest challenges in entering the Japanese market. This could be combined with the challenges that the agreement affects in order to see where they overlap. See Figure 4 for an illustration of this approach.
The figure below illustrates the approach where the factors that are found in the theory (EPA) are mapped together with the factors that are found in the empirics (case study), in order to see where they overlap. TX represent factors found in the theory and EX represent factors found in the empirics.

![Diagram showing mapping and overlapping approach](image)

**Figure 4: Illustration of the mapping and overlapping approach (author’s).**

### 7.7 Contribution to Research

This master thesis project has contributed to research in four distinct areas.

- Firstly, it has managed to conclude that the Swedish MedTech industry is not directly affected by the EPA. Furthermore, it has managed to compile the indirect and potential effects of EPA on Swedish MedTech companies.
- Secondly, through interviewing companies in Japan, the project has assisted in clarifying how much knowledge the companies have about the EPA. From the interviews conducted in this project, it can be concluded that the companies have acquired enough knowledge to know that they are not directly affected.
- Thirdly, a compilation of actors involved in the EPA has been done from a Swedish/MedTech point of view.
- Fourth and last, the insight of the EPA not being a *magic-deal* for MedTech companies planning on conducting business in Japan. If a company has not been able to compete in Japan previously, they will not likely be able to after the implementation of the EPA either.

Above is a list of the contribution to research from the master thesis project.
References


Available at: https://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr_e.htm
[Accessed 08 12 2019].
Appendix

Appendix 1 - Issue Tree Research Questions

In the figure below the research questions are illustrated in an issue tree that was used for the development of the questions.

Figure 5: Issue tree used for the development of the research questions (author's).
Appendix 2 - Interview Guide for MedTech and Life Science Companies

Introduction
1. Introduce ourselves and our project
2. Is it okay if we use material from this meeting in our empirics?
3. Is it okay if we record the meeting?

Interview object overview
1. What do you work with?
2. How long have you been at the company?

Company overview
1. What is your main business?
2. What products/services do you offer on the Japanese market?
3. How big part of your business in Japan?
4. How long have you been active on the Japanese market?
5. What are the biggest challenges of being on the Japanese market?

EPA related questions
1. Did you know about the EPA?
   a. Has it affected you?
      i. Positively?
         1. For your existing business?
         2. Opened new business opportunities?
         3. Other aspects?
      ii. Negatively?
         1. Increased competition?
         2. Other aspects?
      iii. Have you made any adjustments due to the agreement?
   b. How did you get information about EPA?
   c. Do you know about the committees/organizations negotiating with the Japanese government in order to improve the business climate for MedTech?
      i. If yes: What’s your relationship with them?
      ii. Did you know that EPA has improved their negotiation position?
      iii. Do you know what they are working with currently?
         1. Would it have an impact on your business?
      iv. What changes/policies would be the most beneficial for your business?
Appendix 3 - Interview Guide for Organizations Connected to the EPA and/or the MedTech Industry

Since the people we interview have a very different background/expertise/role we use a more unstructured interview guide. Questions will develop depending on the interviewee’s answers during the interview. However, we will try to focus on the EPA and the effect on the MedTech industry if possible.

Introduction

1. Introduce ourselves and our project
2. Is it okay if we use material from this meeting in our empirics?
3. Is it okay if we record the meeting?

Interview object overview

1. What do you work with?
2. How long have you been at the company/organization?
3. What is the function/business of your company/organization?

EPA related

1. What do you know about the EPA?
   a. Questions adjusted depending on the answer above.
2. What has your company/organization’s role been in the development/implementation of the EPA?
   a. Questions adjusted depending on the answer above.