
ECONOMIC TENDENCIES OF THE EUROPEAN AND LATVIAN MEDICAL DEVICE MARKET

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Abstract. Due to ageing of the population in developed countries and increase of the demand for the healthcare worldwide, the industry of medical devices (MD) becomes one of the fast-growing businesses. The present paper analyses the current state of the MD sector in Europe and in Latvia on the basis of the data obtained from open sources. Review of the current situation in the MD sector has demonstrated that the MD field still is and will remain an attractive sector of economics. The growth of the EU MD market by 3.5 % per year is sustainable. The market is highly innovative and leaves enough room for small and medium-size enterprises that provide up to 95 % of all MD sector turnover. This indicates that MD sector manufactures products with high added value that make the sector attractive for countries with limited resources, such as Latvia. Although key players on the market do not change much, example from Ireland demonstrates that investment in human capital is an important pre-requisite for country's success in the MD sector. Unfortunately, the development of the MD industry in Latvia is very slow, the growth is around 0.7 % per year that may be explained just by inflation. There is also a lack of information on the Latvian MD industry both for professionals and society.

Keywords: *Medical device market, Turnover, Employment, Europe.*

JEL Classification: M21, O12

INTRODUCTION

Medical technologies provide value in different ways. They allow people to live longer and better lives, thus empowering them to contribute to society for long. At the same time, medical technologies improve the quality of care, as well as the efficiency and sustainability of healthcare systems. This is especially important nowadays, as the aging of the population stimulates growing demand for healthcare worldwide.

The latest advances in genomics and cell biology have opened ways to the treatment of diseases at the cell level. Modern electronics gave rise to miniaturised data acquisition and communication tools that allowed possible telemetric systems to measure previously inaccessible physiological parameters in real time. Medical devices help in diagnostics and treatment of diseases, provide life support for critically ill patients, replace organs and body parts, monitor physiological condition of high stress professionals, such as fire-fighters or soldiers, and follow activities of the elderly people.

Therefore, the industry of medical devices (MD) is one of the most attractive and profit-promising. The European market of medical devices demonstrated growth even in the recession of 2007–2009, providing an average growth of 4.2 % in the period of 2008–2013 (Maresova *et al.*, 2015).

Manufacturing of medical devices does not require many natural resources; therefore, it could be attractive to small countries with low levels of natural resources. Good examples are the Netherlands, Switzerland, and Ireland. In Latvia, the MD market tripled from nearly 10 MEUR in 2005 up to 27 MEUR in 2015 (Semjonova, 2017), which is in line with world tendencies. Researchers expect a continuous moderate growth of the worldwide MD industry in future as well (Maresova *et al.*, 2015).

Because of wide diversity of medical devices and high and steady demand, small and medium-size enterprises (SMEs) can easily co-exist with large companies. For instance, in China, manufacturers of medical devices are mainly small companies that employ up to 50 people. A similar situation is in Europe, where SMEs comprise 95 % of all companies in the field of medical devices.

At the same time, the MD sector is one of the most complicated for innovation and deployment of new products. The field of medical devices is one of the most strictly regulated (Altenstetter, 2012). Although new European Regulation on medical devices foresees a simplified procedure to put in use innovative medical devices, the placement of the devices on the market still requires much effort. For some cases, a manufacturer has to carry out time-consuming clinical studies to put the device on the market. Another factor hindering the launch of new products on the market is the complicated regulation with regard to medical tests on animals.

Because of the need to comply with regulation requirements, the time and resources that are required to put new medical devices on the market are significant. In pharmacy, product development could last up to 10 years and cost 1 bil. \$ (Mendoza, 2017). This is especially actual for enterprises trying to enter the market for the first time: their expenditures could be 7 % higher than expenditures of the company that already has products on the market (Stern, 2017). Another problem for a small country is a limited size of the local market that forces enterprises to go abroad, to much more regulated international market (Salabarria *et al.*, 2017). This problem, as well as unawareness of possible funding sources and lack of financial skills make difficult the development of small and medium-sized enterprises in the MD industry sector in such a country as Latvia.

The development of the MD industry is closely related to the progress in medical technologies itself; therefore, MD manufacturers have to update their products regularly to keep pace with development of medical technologies. Despite strict regulation, the medical device market is among the most innovative markets. Therefore, companies need highly educated and skilled professionals in the field of medical devices with the knowledge of state and international regulations and competencies in innovation management. This requires sound investment in human resources in addition to the investments in R&D itself. That is why commercialization of innovative medical devices could take from 5 to 10 years.

Except of the strict regulation issues, researchers worldwide discuss a number of problems typical of the MD field. One of such problems is evaluation of the

efficacy and effectiveness of the medical devices that often is a key procedure in clinical evaluation of the devices prior to their placement on the market or related to the decisions about reimbursement of costs by governmental bodies. Several authors pointed out high variability and biases in evaluation methods, mainly based on expert opinion and lack of objective and straightforward methodologies for such evaluations (Bojke *et al.*, 2017, Tarricone *et al.*, 2017).

The developers of the new MD technology need to address properly evaluation of the competitiveness of the developed products at all development stages (Kudryavtseva *et al.*, 2017), as well as keep close contacts with potential users and stakeholders. Lack of such communication could put at risk the whole product success (Markiewicz *et al.*, 2017). The concurrence in the MD field has become especially topical in recent years due to the development of budget – class products and byers' tendency to prefer such products (Llewellyn *et al.*, 2015). Concurrence forces experienced companies to reduce prices, but this tendency should be considered when entering the market as well.

Other problems related to the MD field include occasional disclosure of the classified data in the approval process (Chen, 2017), cyclic behaviour of MD market (Guerrero *et al.*, 2017), dependence of MD technology on the overall technological level in the country (Kim *et al.*, 2017). Apart from the market entry issue, MD manufacturers are obliged to comply with postmarked product vigilance requirement (Zippel *et al.*, 2017).

Only few papers concerning financing opportunities for the MD project could be found (Mas & Hsueh, 2017). Generally, there is a lack of publications that would provide a comprehensive insight into how such factors as regulation requirements, model of healthcare financing, efficacy of communication with stakeholders, level of technological development etc. affect innovation success of the MD field. Such insight would help both developers and investors to assess perspectives and risks of the MD projects.

The aim of the paper is to provide an insight into the development of the MD sector in Europe in order to evaluate the present situation and draft some perspectives for future development with a special focus on the perspectives of Latvia in this sector. To achieve the aim, the research comprises:

- review of literature on the medical device industry;
- review of international legislation, regulating the medical device sector in Europe;
- analysis of the current situation in the European and Latvian MD market.

Research is based on the analysis of data from publicly available databases. Methodology section describes the selected data sources and limitations set for data analysis. Result section provides the results on the MD sector research in Europe and Latvia. Discussion section analyses factors that have an influence on the development of the MD industry. Conclusion provides a general summary of the results, practical recommendations and suggestions for future research.

1. MATERIALS AND METHODS

Information on the development of the MD sector in Europe was summarised on the basis of three annual reports published by the European trade association for the medical technology industry including diagnostics, medical devices and digital health – MedTech Europe. The review included publications that covered the period from 2014 to 2018 [MedTech Europe 2015 – 2020]. The present paper excluded in vitro medical device data.

The data about the Latvian MD industry were retrieved from public available data of the Enterprise Register of Latvia (Firmas.lv, 2020) and the catalogue of medical devices provided by the State Agency of Medicines (ZVA, 2020). Only companies dealing with manufacturing of medical devices were considered; retail/service companies were excluded.

To assess efficiency of the development of the MD industry sector, the growth rate over five observation years was calculated using the data on annual turnover in the MD sector.

The author met some difficulties while retrieving information on the Latvian companies from databases. There were a number of companies – manufacturers of clothing, underwear, shoes, and goods for sport – that produced both medical devices and general-purpose goods. This made it difficult or even impossible to separate turnover related to medical devices from the general turnover of an enterprise. Therefore, the author applied a set of assumptions to bring information closer to the real situation. Turnover of Lauma Medical company for the period up to 2018 was estimated at the level of 5 % from the total turnover of its parent enterprise Lauma Fabric. Lauma Medical was established as a separate enterprise just in 2018 and the only available report covered the period of 30 May 2019–31 December 2019, providing turnover for 7 months. These data were recalculated to estimate turnover for 12 months (multiplying by 12/7). Resulting turnover comprised 5 % of turnover of the parent enterprise; thus, 5 % was used as an estimate of part of the parent enterprise turnover related to the medical device manufacturing. Two enterprises were censored because manufacturing was placed in Lithuania. Data on five enterprises were censored after 2016, since companies stopped manufacturing and were dealing entirely with distribution and retail.

Alongside, as the date of the annual report for Ceram Optic company was 30 June, the data for 2019 were duplicated from 2018.

2. RESULTS AND DISCUSSION

Medical technology is characterised by a constant flow of innovations, which are the result of high-level research and development within the industry, and of close co-operation with the users. Products typically have a lifecycle of only 18–24 months before an improved product becomes available. In 2018, more than 14 000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – 7.7 % of the total number of applications; it was more than in any other sector in Europe. Generally, 39 % of these patent applications were filed from European countries (EU27, the UK, Norway and Switzerland) and 61 %

from other countries, out of which a majority of applications were filed from the US (40 %). In comparison, in the same 2018, only 7679 applications were filed in pharmaceuticals and only 6801 applications – in biotechnology. Over the period of 2007–2018, the number of patent applications in the MD field steadily increased from 9500 in 2007 up to more than 14 000 in 2018, while the number of patents in pharmaceuticals and biotechnology was relatively stagnant and varied slightly about the level of 6000–7000 applications per year between 2007 and 2017, with a slight increase in 2018.

In the considered period, the world market demonstrated a high level of stability concerning the role of major players. Figure 1 demonstrates the distribution of the MD market turnover. Now, the USA is the main player on the market, and its contribution to the world MD market increased over a 5-year period from 39 % up to 43 %. Contribution of Europe as a whole and Japan decreased from 31 % to 27 % and from 9 % to 7 %, respectively. Together, the USA, Europe and Japan produce about 77 % of the MD products in the world that demonstrates a high level of scientific and technological development in these countries. China steady shares 6 % of the world MD market, Canada – 2%. The contribution of Brazil and Russia decreased from 2 % each in 2014 to below 1 % in 2018. Europe holds around 40 % of all patents in the MD field and only 27 % of the MD sector turnover. This could be an indication of higher quote of small medical devices and lower quote of complex medical equipment in the structure of the EU MD sector. Alongside, a decrease in the EU part of the MD market may indicate a potential problem with the introduction of new products into the market. Implementation of the new EU Medical Device Regulation can solve this problem, as in some extent it opens simplified ways for innovations in the MD field.

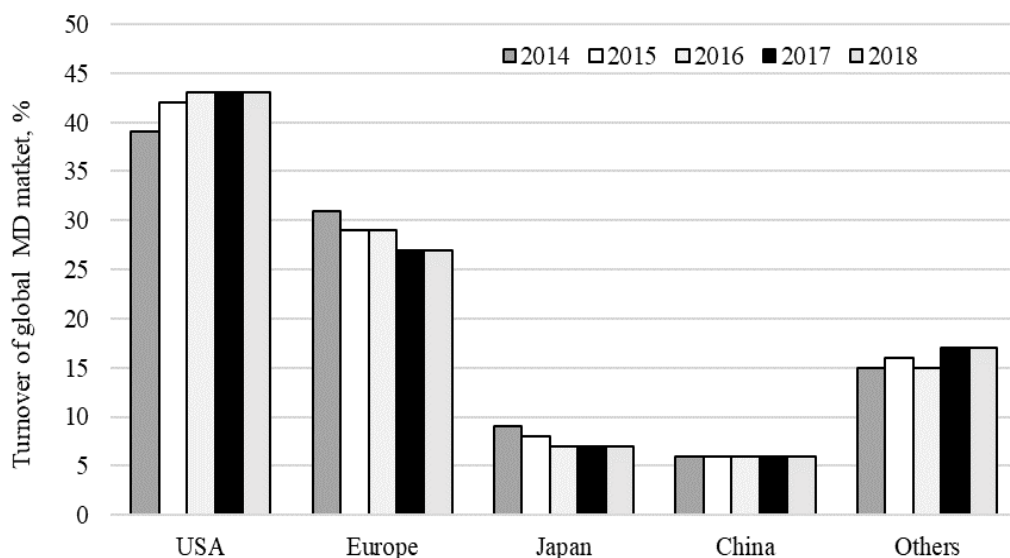


Fig. 1. The main players on the world MD market (developed by the author based on MedTech Europe 2015–2020).

Total European turnover in the MD sector constituted nearly 120 billion EUR in 2018. A detailed analysis of European countries (Fig. 2) demonstrated that Germany, France, the United Kingdom, and Italy provided about 62.8 % of all European MD market turnover. Here Germany is a constant market leader sharing 27.1 % of the market. MD market of France is the second in Europe and constitutes 14.6 %. The positions of leaders did not change much in the period of 2014–2018; typical changes were within 1 %. In 2018, Poland improved its position by reaching the market share of 2.6 %, which is more than that of Austria (2.5 %). To compare with other European countries, the Latvian turnover of the MD industry is just 0.02 % of the European one.

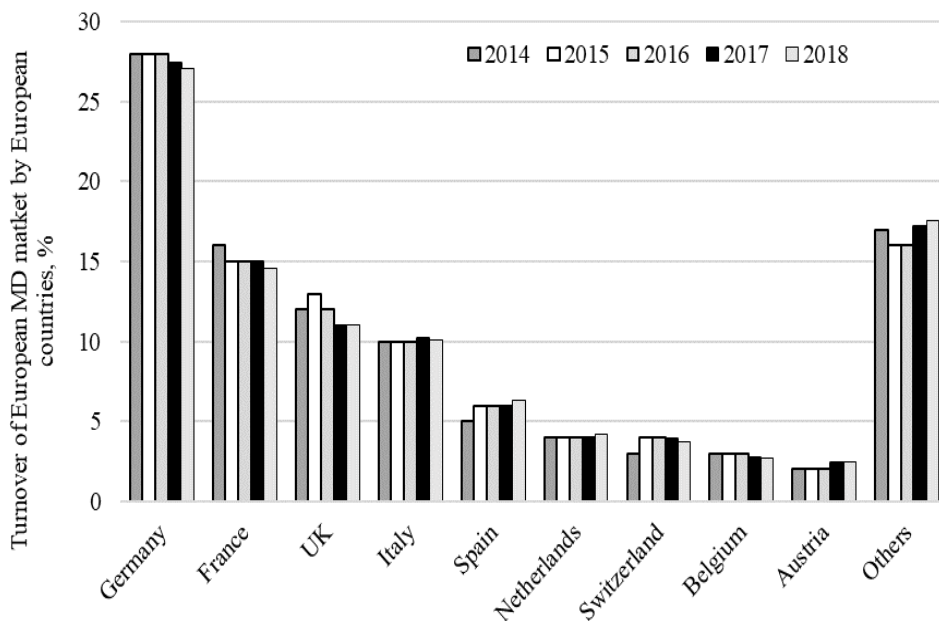


Fig. 2. The main players on the European MD market (developed by the author based on MedTech Europe 2015–2020).

Despite high turnover indicators, EU leaders in the MD field fall apart in the number of employers in the MD field. In total, there were more than 730 000 people directly employed in the MD field in Europe in 2018. Still, Germany has the highest absolute number of people employed in the MD sector (227 700 people in 2018, MedTech Europe data), while the figures per 10 000 inhabitants are somehow different. Figure 3 illustrates employment in the MD sector in European countries. The number of MD employees per capita is highest in Ireland and Switzerland. Ireland is an especially interesting example, as the number of the MD sector employees demonstrated fast growth. The MD sector turnover of Ireland was not high in absolute figures – it was about 0.65 billion EUR in 2016 (Emergo by UL, 2019). Now products of the MD industry constitute about 8 % of all export of Ireland (IDA Ireland, 2020). In 2018, other countries except those mentioned in Fig. 3 were added to the MedTech Europe report due to a noticeable number of employees in the MD sector: Hungary (12 employees per 10 000), Austria (10), Finland (7). In Latvia, there are only 3.4 employees in the MD sector per 10 000

inhabitants that, on the one hand, indicates a rudimentary state of the MD sector in Latvia and, on the other hand, shows that there are some development perspectives. Latvian data are compatible with those of such countries as Portugal, Slovakia or Romania, each having 3 employees in the MD sector per 10 000 inhabitants in 2018. Generally, the high level of employment in the MD sector shows that the medical technology industry is an important player in the European economy. Alongside, analysts consider jobs in the MD sector highly productive, generating added value on average of € 160 000 annually per employee.

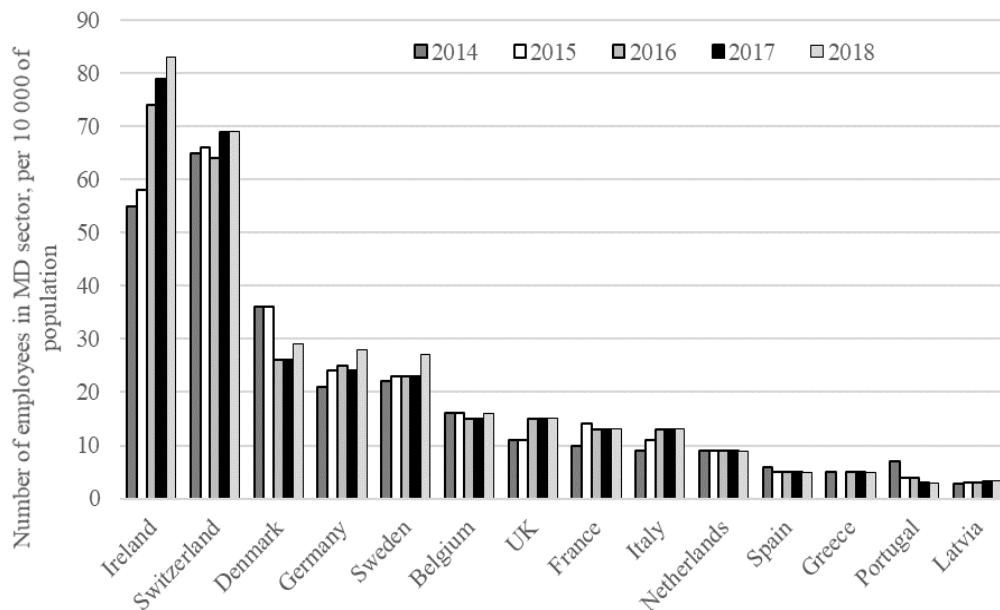


Fig. 3. Number of employees in the MD sector in Europe (developed by the author based on MedTech Europe 2015–2020).

There are almost 32 000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain, and France. Small and medium-sized companies make up around 95 % of turnover of the medical technology industry, most of those companies are small enterprises that employ less than 50 people.

In Europe, approximately 10 % of gross domestic product (GDP) is spent on healthcare. Out of the total healthcare expenditure, around 7.3 % is attributed to medical technologies that constitutes less than 1 % of GDP. Spending on medical technologies is estimated to vary significantly across European countries, ranging from around 5 % to 10 % of the total healthcare expenditure. Average per capita expenditures on medical technology in Europe demonstrate a steady growth in the considered period from € 195 in 2014 up to € 225 in 2018 [MedTech Europe 2020].

The gross turnover of the MD sector in Europe demonstrated a steady growth from 100 billion EUR in 2014 up to 120 billion EUR in 2018 (Fig. 4), which corresponded to an average annual growth of 4.0 %. In Latvia, turnover of the MD sector grew to 10.7 % per year, increasing from 30.9 mil. EUR in 2014 up to

47.9 mil. EUR. Such a growth rate more than twice exceeds the European average (Fig. 5). Alongside, in 2019, the Latvian MD industry grew by 26.9 %. Such figures demonstrate high potential of the MD manufacturing sector in Latvia. On the other hand, such a high growth rate could be due to a low initial position of Latvia in the MD market. A detailed analysis demonstrates that such a high rate is provided, to a great extent, by only one company, manufacturer and exporter of medical grade optical fibres (Light Guide Optics International, Ltd). The turnover and export of this company has increased rapidly since 2016.

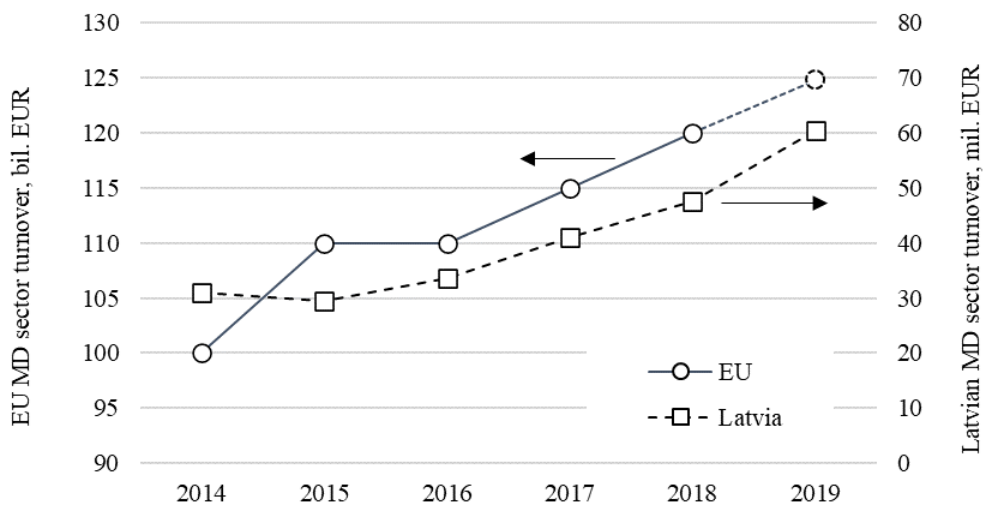


Fig. 4. Gross turnover of the MD sector in Europe and Latvia (developed by the author based on MedTech Europe 2015–2020, the author’s calculations). The EU data for 2019 are forecast using an average growth rate of 4.0 % per year.



Fig. 5. The MD sector growth rate in Europe and Latvia (developed by the author based on MedTech Europe 2015–2020, the author’s calculations).

One should note that the analysis of the Latvian market is complicated by a lack of information. Even though the MD market is very important for the social sector, it is not separated in state reports as a distinct sector of the market (Latvijas banka, 2018; CSP, 2020). Although the databases of the Central Statistical Bureau of Latvia contain some information on manufacturing and trade of medical devices by type, there are no consolidated data. In addition, the used classification differs from the NACE classification. Although the state sustains the register of MDs admitted to the Latvian market (ZVA, 2020), there is no clear requirement for entrepreneurs to remove the dated MDs from the register. This distorts the information and does not provide an opportunity to fully assess the scale of the market.

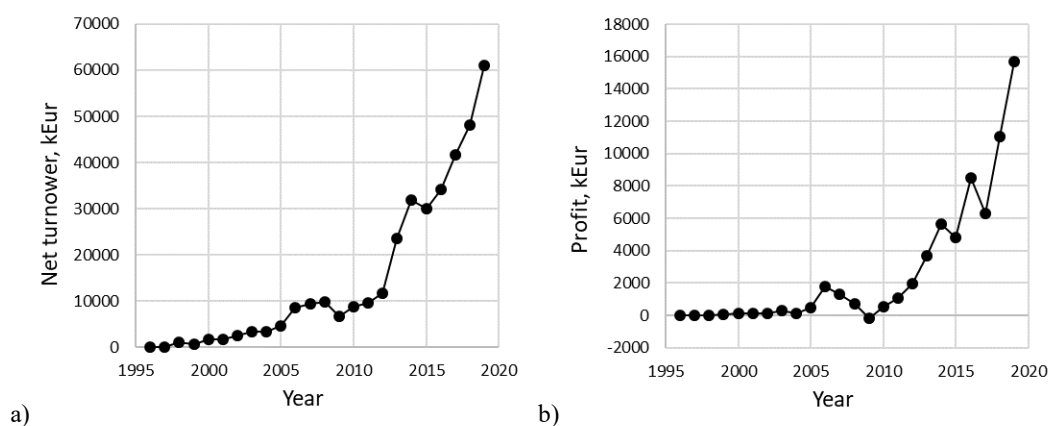


Fig. 6. Turnover (a) and profit (b) of the MD sector in Latvia, 1996–2019 (the author's calculations).

A detailed analysis demonstrates that the development of the MD market in Latvia follows the European trend. The growth is steady, with minor drops in 2008 and 2015. The causes of these drops seem to be somehow different: while comparing Fig. 6a with Fig. 7, demonstrating the turnover of the five leading MD manufacturers, one could note that the total turnover in Fig. 6a mostly follows the turnover of a leading manufacturer. This is because of an extremely small size of the Latvian MD manufacturer market, when one company can account for significant variation in the turnover. The drop in 2008, certainly, could be related to 2008 recession, when turnover of the company Tonus Elast decreased. In turn, the drop in 2015 is related to a decrease of turnover of Ceram Optics company. As there was no global economic recession in 2015, this decrease could be related to the company's internal affairs.

The profit in the MD manufacturing sector is significantly positive with a growth tendency, although some fluctuations were observed (Fig. 6b). Since the market indicators depend strongly on the profit of several leaders, such fluctuations could be explained by variation in the profit of separate players.

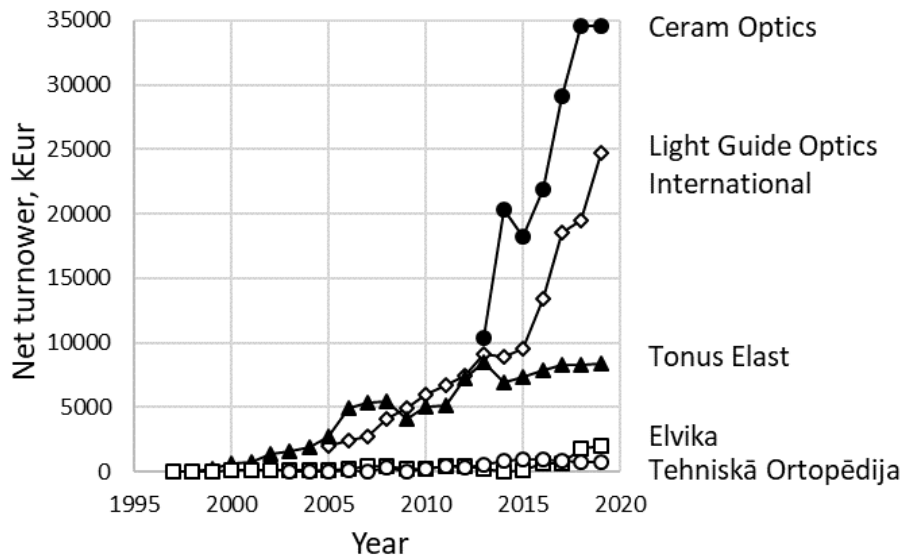


Fig. 7. Turnover of the top five MD manufacturer enterprises in Latvia, 1996–2019 (the author's calculations).

Figure 8 demonstrates the turnover of the five leading companies in the MD manufacturing sector in Latvia. There are three leaders that are actually ahead of all other market players. Two of these companies – Ceram Optics and Light Guide Optics International – have been established relatively recently (in 2013 and 2004, respectively). Besides, they were created on the basis of enterprises with 40–50 years of experience in the market and the established trading contacts. Both these young companies demonstrated extremely fast growth that could be explained by the inflow of foreign investment and increased demand for the company production in the world market.

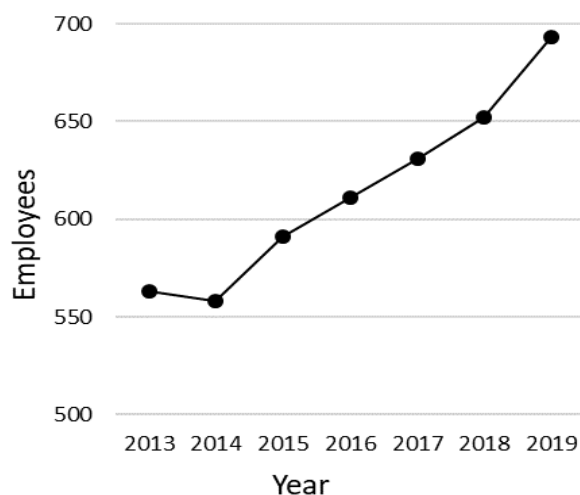


Fig. 8. Employment in the MD manufacturing sector in Latvia (the author's calculations).

Other leading companies – Tonus Elast, Elvika, Tehniskā ortopēdija – did not show so fast increase in the turnover. Nevertheless, they demonstrated steady growth, as well. The analysis of these Latvian enterprises shows that despite numerical difficulties, companies, financed by local capital can develop and gain sustainable turnover growth.

The growth of the MD manufacturing sector in Latvia is characterised by the steady increase in the number of employees, too (Fig. 8): the annual increase was 19 %.

Figure 9a demonstrates that the MD field is perspective from the profitability point of view: profit margin ratio generally increased and fluctuated around 15–25 %. Due to the small market size, consolidated indicators are extremely sensitive to the success or pitfalls of individual companies. For example, a sharp decrease of up to –3 % in 2009 was related to significant losses of Lauma company. Nevertheless, already in 2010 company compensated all loses and regained profit. Generally, high profitability of the MD sector could be explained by a steady increase in demand for MD products.

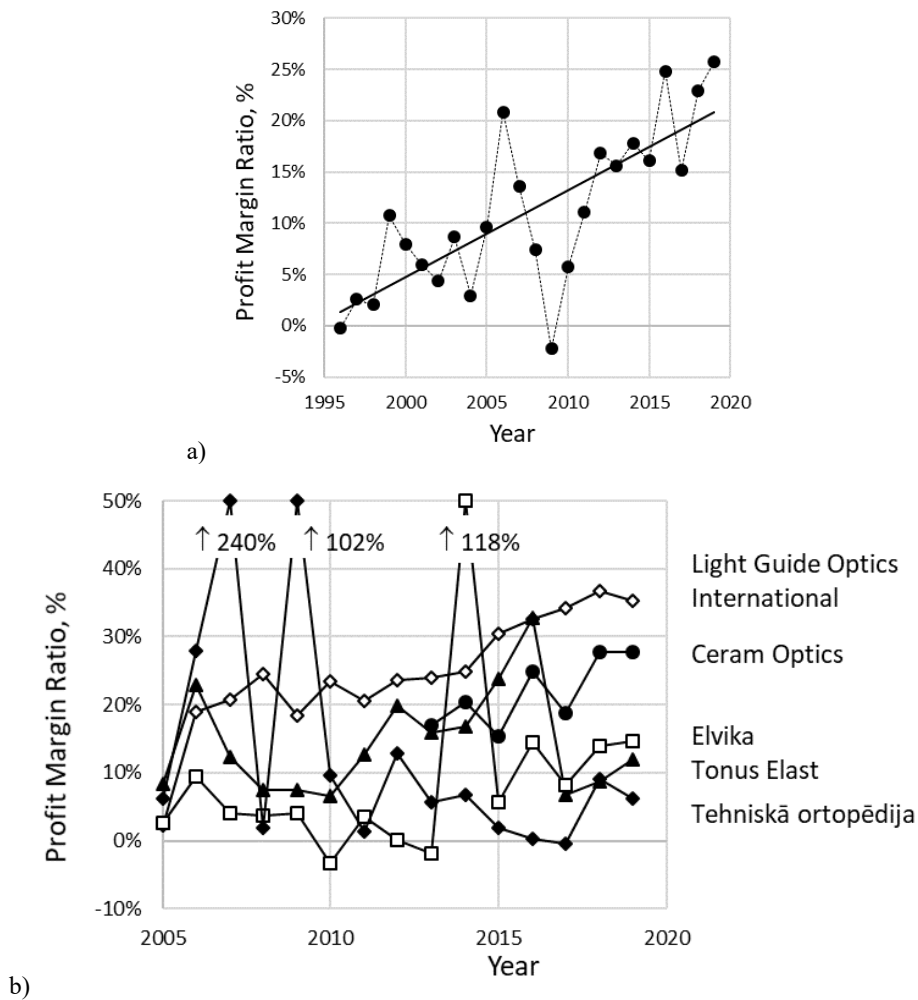


Fig. 9. Profit margin ratio in the MD manufacturing sector in Latvia (the author’s calculations).

Figure 9b shows a profit margin ratio for five leading companies in the MD sector – the same companies, as in Fig. 7. The analysis was limited to the period from 2005, when Latvia joined the EU and companies adjusted their manufacturing process to the EU requirements. Figure 9b indicates that companies with greater turnover demonstrate higher profitability, too. Within the analysed period, some companies had extremely high profit, e.g., profit of Tehniskā ortopēdija reached 240 % in 2007, but in 2009 – 102 %. In turn, Elvika company demonstrated 118 % profit in 2014. Such high profit could be related to state financed tenders.

CONCLUSIONS

Review of the current situation in the MD sector demonstrated that the MD field still is and will remain an attractive economic sector. The EU MD market growth of 4.0 % per year is sustainable. The market is highly innovative and leaves enough room for small and medium-sized enterprises that provide up to 95 % of all MD sector turnover. This indicates that the MD sector manufactures products with high added value that make the sector attractive for countries with limited resources, such as Latvia. Although the key players of the market do not change much, an example from Ireland demonstrates that investment in human capital is an important pre-requisite for country's success in the MD sector. Development of the MD industry in Latvia demonstrates a noticeable growth of 10.7 % per year that more than twice exceeds the European average. There is a lack of information on the Latvian MD industry both for professionals and society.

Analysis of the Latvian MD manufacturers demonstrates a positive sustainable growth. Difficulties, such as the need to cope with requirements of the EU directives and national legislation, economic recessions, and high level of concurrence, do not hinder the development of the Latvian MD manufacturing sector. The MD market is wide, and the assortment of MD is very broad that allow for successful co-existence of both large and small companies in the market. This, in turn, implies that Latvia could have a perspective in the development of small MD-oriented manufacturing companies.

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