Poland.

Industry characteristics

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Basic information

In Poland, the pharmaceutical industry and the production of medical devices underwent significant changes following the economic transformation of the early 1990s, including the privatization of companies and the harmonization of regulations with EU standards, which facilitated exports. The low level of domestic production of basic pharmaceutical substances and dependence on imports pose a challenge to the country's medicine security.

Japan, as one of the world's largest producers of medical devices and pharmaceuticals, has a highly regulated market with advanced infrastructure and innovative technologies. The process of registration and regulatory approval for medical devices in Japan is complex and costly, requiring experience and a local partner.

Both Japan and Poland rank among the top twenty global exporters and importers in this sector; however, both countries hold higher positions as importers (Japan – 6th; Poland – 16th) than as exporters (12th and 20th respectively), with Japan maintaining a relatively stronger position in international trade in this industry.

Pharmaceuticals play an important role in global trade within the sector, as well as in the trade of both countries. However, the export structures of pharmaceuticals differ: Japan has a high share of domestic value added in exports, while Poland has a relatively higher share of foreign value added, with the country's competitive advantages largely resulting from lower production costs.

In bilateral trade between Poland and Japan, the share of medical and pharmaceutical products has been gradually increasing, although it remains modest. In Polish exports to Japan, the share of this sector rose from 1.8% in 2015 to 4.5% in 2022, while in Polish imports from Japan the share remained stable, fluctuating around 2.5%.

The most important product group in Polish exports to Japan is orthopaedic equipment, while in Polish imports from Japan the leading items are instruments and devices used for medical, surgical, dental, or veterinary purposes, as well as pharmaceuticals.

The potential for bilateral cooperation between Poland and Japan in the medical and pharmaceutical sector lies particularly in trade in pharmaceuticals and medical equipment, especially orthopaedic equipment. Orthopaedic products exported from Poland to Japan show the highest growth dynamics compared to other product groups in the sector and are already gaining a foothold in the Japanese market. Pharmaceuticals may also be a promising area of cooperation due to the complementary export structures of both countries and the growing demand driven, among other factors, by ageing populations.

An analysis of the development of the medical and pharmaceutical industry shows considerable, but still underutilised potential for the development of mutual business and R&D relationships. The industry, which is crucial for the health and well-being of the population of both countries, plays a strategic role in the economy. In Poland, the pharmaceutical industry and medical devices manufacturing underwent major changes after the political transition in the early 1990s. This included the privatisation of companies and the harmonisation of regulations with EU standards, which facilitated exports. The low level of production of basic pharmaceutical preparations and the dependence on imports pose a challenge to the country's drug safety. Japan is one of the world's largest manufacturers of medical devices and pharmaceuticals and has a highly regulated market with advanced infrastructure and innovative technologies. The process of registration and regulation of medical devices in Japan is complex and expensive, which requires experience and a local partner.

Based on the analysis of the medical and pharmaceutical industry trade, the following conclusions can be drawn:

The medical and pharmaceutical industry is of strategic importance in the economy due to its key role for the health and well-being of society.

Both Japan and Poland are among the top twenty exporters and importers of this industry worldwide. Both countries rank higher as importers (Japan – 6th place; Poland – 16th place) than as exporters (12th and 20th place respectively), with Japan occupying a relatively stronger position than Poland in international trade in products from this industry.

Pharmaceutical products play an important role in the global trade of both countries, but the export characteristics of pharmaceuticals are different for Poland and for Japan. Japan has a high share of domestic value added in exports, while Poland has a relatively higher share of foreign value added in exports, and our country's trade advantages are largely due to lower costs.

In Poland's bilateral trade with Japan, the share of medical and pharmaceutical products is gradually increasing, but is still of minor importance. In Polish exports to Japan, the share of products from this industry increased from 1.8% in 2015 to 4.5% in 2022, while in Polish imports from Japan the share of these products was stable and fluctuated around 2.5%.

The most important product group of this industry in Polish exports to Japan is orthopaedic equipment, and in Polish imports from Japan – medical, surgical, dental or veterinary instruments and devices as well as pharmaceuticals.

The potential of Poland's bilateral cooperation with Japan in the medical and pharmaceutical industry can be sought in the field of trade in pharmaceuticals and medical devices, in particular orthopaedics. Orthopaedic devices and their exports from Poland to Japan are characterised by the highest growth dynamics compared to other product groups in the medical and pharmaceutical industry. Pharmaceuticals, on the other hand, could be an interesting area for cooperation, as the export structures of both countries complement each other with regard to this product group and demand in both countries is increasing, partly due to the ageing society.

Development of the medical and pharmaceutical industry in Poland

After the political transformation in the early 1990s, the Polish pharmaceutical industry and the industry involved in the manufacture of medical products changed fundamentally. These changes affected the ownership structure of companies in the sector, the rules for marketing medicines, the administrative system for the management of public health service, etc. Pharmaceutical companies in Poland were privatised, with many of them being taken over by pharmaceutical corporations from abroad. The rules for trade in medicines were harmonised with the standards of the European Union, which facilitated the export of Polish pharmaceutical and medical products to foreign markets. These regulations also included the registration of medicines, quality control and test procedures.

Value of marketed production of products of the medical and pharmaceutical industry in Poland in 2022 at producer's prices

Specification	Value of marketed production	
	Value in PLN million	Share in the total value of marketed production of manufacturing products
Manufacture of medical and dental instruments and supplies	5614.6	0.3
Manufacture of pharmaceutical products including:	14314.6	0.8
Basic pharmaceutical preparations	708.9	0.1
Pharmaceuticals and other pharmaceutical products	13605.7	0.7

Source: a study based on databases assigned to a publication by the Central Statistical Office [2023].

The data from the table above show that the total value of marketed production of products of the two analysed industries in Poland in 2022 accounted for only 1% of the total value of marketed production of manufacturing products, while the value of production of pharmaceutical products (PLN 14314.6 million) was about 2.6% higher than the production of medical and dental instruments and supplies. At the same time, within the pharmaceutical industry, the low production of basic pharmaceutical preparations compared to the production of pharmaceuticals and other pharmaceutical products indicates that basic pharmaceutical preparations are imported from other countries to Poland. This means that Polish pharmaceutical production is dependent on external supplies, which poses a threat to drug safety. This was clearly demonstrated by the disruption of global value chains as a result of the COVID-19 pandemic crisis.

A more detailed analysis of the products of the medical and pharmaceutical industry in Poland is possible thanks to the data of the Central Statistical Office (GUS) presented in table belowwhich is available for entities with 50 or more employees operating in 2022.

According to the data in the table below, the number of business entities employing more than 50 people and operating in 2022 was the same in both categories analysed, while in the manufacture of pharmaceutical products they reached a higher level in terms of marketed production, employment, monthly salary and gross value of fixed assets. It should be noted that pharmaceutical products, as products for the consumer sector, have much greater economies of scale than medical devices, which mostly include products for the "corporate" sector (doctors' surgeries, hospitals, outpatient clinics, etc.).

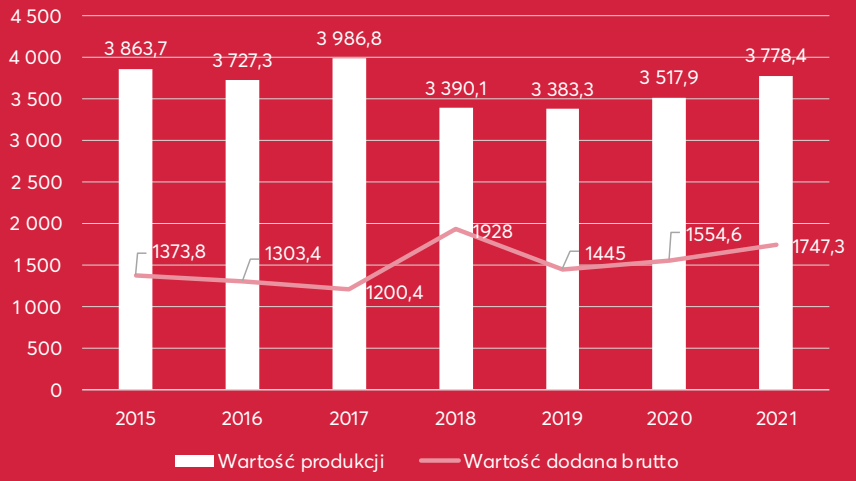
Characteristics of the medical and pharmaceutical industry in Poland, 2022

Specification	Economic operators	Marketed production, in PLN million	Average number of employees in thousands	Average gross monthly salary, in PLN	Gross value of fixed assets, in PLN million
Manufacture of pharmaceutical products	72	16054.4	25.4	8891.23	13186.3
Manufacture of medical and dental instruments and supplies	72	6227.9	16.0	6418.91	4170.7

Source: a study based on databases assigned to a publication by the Central Statistical Office [2023].

Wartość wyprodukowanych farmaceutyków w Polsce utrzymuje się na względnie stabilnym poziomie, przy czym odnotowano niewielki spadek z 3863,7 mln EUR w 2015 r. do 3778,4 mln EUR w 2021 r. Jednocześnie zwiększeniu uległa wartość dodana brutto z 1373,8 mln EUR do 1747,3 mln EUR w 2021 r. Stabilny poziom wartości wyprodukowanych farmaceutyków w Polsce przy jednoczesnym wzroście wartości dodanej brutto może świadczyć o zwiększeniu efektywności produkcji i lepszym zarządzaniu kosztami produkcji. Jednakże udział krajowego przemysłu farmaceutycznego w polskim PKB spada, co oznacza, iż sektor ten jest coraz bardziej uzależniony od dostaw z zagranicy.

Production value and gross value added of the pharmaceutical industry in Poland, in EUR million, current prices



Source: a study based on Eurostat databases [nama_10_a64], database last updated on: 07.06.2024 [accessed on: 15.06.2024].

Structure of enterprises in the pharmaceutical industry in 2022.

Specification	Total	Number of employees (in absolute terms)					
		49 and less	50–99	100–249	250–499	500–999	1000 and more
Number of entities	124	51	22	21	16	10	4
Marketed production (PLN million)	16492.7	392.4	691.1	1567.4	3364.7	4731.9	5745.2
Average number of employees (thousands)	26.5	1.1	1.6	3.2	6.0	6.8	7.8

Source: a study based on databases assigned to a publication by the Central Statistical Office [2023].

W Polsce w 2022 r. funkcjonowało 124 producentów wyrobów farmaceutycznych, odpowiadających za ponad 16 492,7 mln PLN produkcji sprzedanej. Biorąc pod uwagę strukturę wielkościową przedsiębiorstw z badanego sektora, można zauważyć, iż stosunkowo wysokie wyniki w tym zakresie osiągają podmioty małe, o zatrudnieniu nieprzekraczającym 49 osób. Ich udział w ogólnej liczbie przedsiębiorstw w 2022 r. wynosił około 41%. Podmioty te odpowiadały wówczas za zaledwie 2,4% ogólnej wartości produkcji sprzedanej wytworzonej w przemyśle wyrobów farmaceutycznych. Firmy średnie, zatrudniające od 50–249 osób, stanowiły natomiast 34,7% ogółu przedsiębiorstw oraz wytwarzały 13,7% produkcji sprzedanej. Dominujący udział w produkcji sprzedanej przemysłu farmaceutycznego (84%) stał się zaś udziałem dużych podmiotów, o zatrudnieniu na poziomie powyżej 250 osób, mimo iż stanowiły one tylko 24,1% ogólnej liczby przedsiębiorstw. Podobne zależności można zauważyć, analizując udział w zatrudnieniu poszczególnych grup przedsiębiorstw. Udział dużych przedsiębiorstw w zatrudnieniu ogółem w przemyśle farmaceutycznym w 2022 r. wyniósł 77,7%, podczas gdy odsetek małych i średnich przedsiębiorstw ukształtował się w tym przypadku na poziomie odpowiednio 4,2% i 18,1%.

Development of the medical and pharmaceutical industry in Japan

As one of the world's largest manufacturers of medical devices and pharmaceutical products, Japan remains an important centre of innovation in these industries. There are two regulatory authorities responsible for the regulation of medical devices in Japan: Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). The MHLW is responsible for administrative activities, e.g. guidelines or decisions for product authorisation under the Product Quality, Efficacy and Safety Assurance Act, including pharmaceuticals and medical devices, and for assessing whether a product qualifies as a medical device. On the other hand, the PMDA reviews products and takes safety measures after they have been placed on the Japanese market

Japan's medical device industry is characterised by a relatively low level of concentration, with no single national player controlling the entire sector. There are many small operators, some of which specialise in niche technologies. Japanese medical device manufacturers enjoy a strong position in the areas of diagnostic imaging equipment, therapeutic and surgical devices, monitoring systems and endoscopes.

The largest players in terms of sales include Fujifilm, Olympus, Canon Medical Systems, Terumo and Nipro. The market for medical devices is driven by the development of high-tech products and an advanced healthcare infrastructure. For example, the Japanese government has taken various measures to strengthen the healthcare system and provided funding for medical research and development.

The Japanese pharmaceutical market is experiencing a surge in demand for innovative medicines, fuelled by the ageing population and the increasing incidence of chronic diseases. Japanese pharmaceutical companies are actively collaborating with artificial intelligence start-ups. The adoption of AI-driven drug discovery techniques in Japan, including the ability to utilise big data for analytical purposes, is enabling pharmaceutical companies to develop and design pharmaceutical compounds faster.

Key factors for the successful launch of medical devices in the Japanese market include:

- the understanding of the regulatory requirements for authorisation, determining the right reimbursement pathway and identifying a good distribution partner,
- the finding of a distribution partner and active participation in industry trade shows in Japan,
- the involvement of a Key Opinion Leader (KOL) who can help with the market launch in Japan.

The key factors for the development of the medical AI market in Japan are as follows):

- the increasing availability of healthcare data, including electronic medical records,
- the increasing cognitive power of computing technology, high healthcare expenditure,
- the need to improve coordination between healthcare professionals and patients,
- the growing demand for precision medicine,
- the shortage of qualified medical professionals,
- the ability of AI to improve patient outcomes,
- an increase in venture capital funding in the field of artificial medical intelligence.

At the same time, there are a number of challenges that are currently limiting the development of the Japanese market for medical AI

- an inadequate regulatory framework and the lack of standards against which regulators can assess the quality of digital systems,
- slow progress in the commercialization of medical AI products,
- the reluctance of patients: concerns about artificial intelligence technology, data protection issues,
- limited acceptance by medical professionals (risk of misinterpretation),
- a lack of talent in the field of artificial intelligence,
- low interoperability of medical data systems,
- the need for clinical validation before the use of algorithms by healthcare providers,
- the need for quality assurance mechanisms for AI-based software as a medical device (SaMD),
- ensuring the quality and privacy of data and the security of medical databases,
- gaining the trust of patients and doctors.

The pharmaceutical industry in Japan is highly regulated, as is the medical device industry. This applies to authorisation procedures, quality control, distribution and price maintenance. Although the regulatory authority, the Pharmaceuticals and Medical Devices Agency (PMDA), is increasingly harmonised with international regulations, pharmacodynamic and clinical studies are often required for the Japanese population. Some documents and many consultations require knowledge of the Japanese language and business culture, so Japanese service providers are requiredAt the same time, the Japanese pharmaceutical market is one of the largest in the world and open to innovation thanks to participation in many international networks.

W okresie od 2015 do 2021 roku liczba producentów farmaceutycznych ulegała wahaniom, jednak ogólna suma producentów pozostała stosunkowo stabilna, z niewielkimi różnicami z roku na rok. Najniższą ogólną liczbę producentów odnotowano w 2019 roku (306), a najwyższą w 2021 roku (330). Największe zmiany w liczbach producentów zauważalne są w mniejszych kategoriach zatrudnienia (1-10 i 11-50 pracowników), podczas gdy liczba dużych producentów pozostaje bardziej stabilna.

Number of pharmaceutical manufacturers by number of employees in Japan, 2015–2021

Year	Number of pharmaceutical manufacturers by number of employees							
	1-10	11-50	51-100	101-300	301-1000	1001-3000	more than 3000	Total
2015	24	61	28	72	70	44	29	**328**
2016	19	55	31	72	68	41	30	**316**
2017	22	60	33	68	65	45	28	**321**
2018	20	51	29	74	73	45	26	**318**
2019	24	46	33	64	68	42	29	**306**
2020	26	51	35	72	68	41	28	**321**
2021	19	64	31	69	73	45	29	330

Source: a study based on databases by the Ministry of Health, Labour and Welfare, Statistics on Pharmaceutical and Medical Device Industry https://www.e-stat.go.jp/stat-search/files?page=1&toukei=00450152&tstat=000001034412 and JPMA [2024].

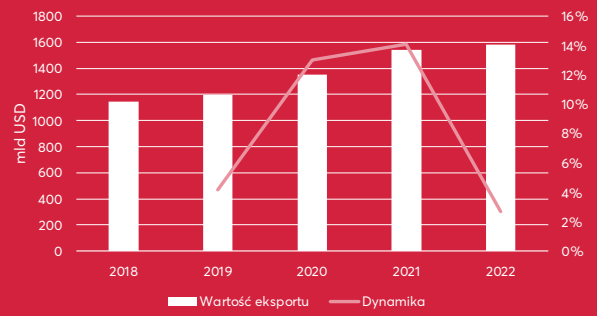
Zarówno całkowita sprzedaż, jak i sprzedaż na mieszkańca wykazują wahania w latach 2015-2021. Szczególnie wyróżnia się spadek całkowitej sprzedaży produktów farmaceutycznych z 77228,4 mln USD w 2015 r. do 60885 mln USD w 2021 r. Wpływ na to mają złożone procesy regulacyjne i cenowe, a także regularne obniżki cen, które utrudniają firmom farmaceutycznym wprowadzanie nowych innowacyjnych produktów. Dodatkowo, na marże zysku firm farmaceutycznych negatywnie wpływa promocja leków generycznych, przyjęta przez rząd w 2007 roku w celu zmniejszenia wydatków na opiekę zdrowotną w Japonii. Leki generyczne to konkretne środki terapeutyczne dostarczane przez alternatywnych producentów po wygaśnięciu patentów na nie – zazwyczaj za niższą cenę niż sprzedają je pierwotni producenci, którzy wprowadzali dany środek na rynek. Udział leków generycznych w japońskim rynku wzrósł ponad dwukrotnie w ciągu ostatniej dekady i nadal rośnie.

Sales of pharmaceutical products in Japan, 2015-2021

	2015	2016	2017	2018	2019	2020	2021
Total sales of pharmaceutical products in USD million, at exchange rate	77228.4	87553.3	87437.9	70638.5	62200	55749.3	60885
Sales of pharmaceutical products in USD per capita, at exchange rate	438.6	479.7	472.9	494.7	690	687.8	666.5

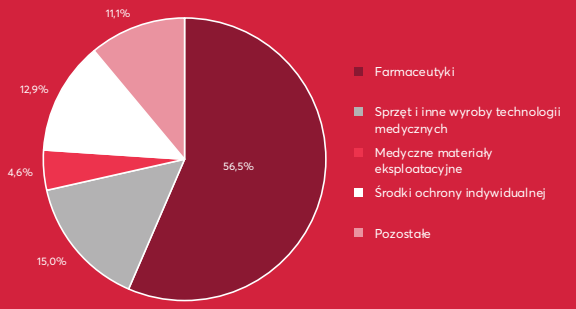
Source: data from the OECD.Stat Pharmaceutical Market database [accessed on 17.06.2024].

Worldwide export of products of the medical and pharmaceutical industry in 2018–2022 (left axis: USD billion; right axis: % change)



Source: study based on WTO data [2023], https://www.wto.org/english/blogs_e/data_blog_e/blog_dta_23may23_e.htm, accessed on: 20.06.2024.

Structure of global exports of medical and pharmaceutical products in 2022 (export shares of the entire industry in %)



Source: study based on WTO data [2023], https://www.wto.org/english/blogs_e/data_blog_e/blog_dta_23may23_e.htm, accessed on: 20.06.2024.

Development trends in the medical and pharmaceutical industry and the potential for expanding Polish-Japanese cooperation

The medical and pharmaceutical industry is one of the most dynamically developing sectors with a high intensity of expenditure on research and development activities. The medical and pharmaceutical industry is one of the dynamically developing sectors with a high intensity of expenditure on research and development activities. According to the classification of the World Trade Organisation (WTO), the products of the medical and pharmaceutical industry are divided into five product groups: pharmaceutical products, medical devices and other medical technology products, medical consumer goods and personal protective equipment.The strategic importance of these products for the medical and pharmaceutical industry stems from the fact that they are crucial for the health and well-being of society. In the first decade of the 21st century, the medical and pharmaceutical industry underwent dynamic structural changes caused by rapid technological development, and this process was accompanied by institutional adjustments.

The COVID-19 pandemic was one of the shocks that affected the change in the functioning of value chains in this industry, which required adjustments at the level of enterprises and market structure.However, the pandemic was an important factor in the dynamisation of trade in the medical and pharmaceutical industry and changed current trends. Goods in the medical and pharmaceutical industry, which accounted for 6.4% of total world trade in 2018, increased their share to 8.3% in 2020.

According to the WTO, the sharp increase in international trade in the medical and pharmaceutical industry during the pandemic was mainly the result of the intensification of trade in personal protective equipment and pharmaceutical products. This positive trend continued in 2021 with a further 14.1% increase in trade in medical devices, mainly due to a significant increase in pharmaceutical exports. In 2022, exports grew by a mere 2.7% and the share of medical devices in total world trade in goods returned to pre-pandemic levels, falling to 6.9%.

Pharmaceuticals are the largest product group in the global exports of the medical and pharmaceutical industry. Their share in the exports of the industry as a whole exceeds 56% and even increased slightly (by 2 percentage points) in the period 2018-2022. The second largest product group in terms of the industry's share of international trade is medical devices and instruments (15% in 2022). This is followed by personal protective equipment (12%), medical consumables (5%), and the rest are other medical devices.

The world's largest exporters of medical and pharmaceutical products are Germany, the United States, China, Belgium and Switzerland. The majority of global imports are dominated by the same countries, but in a slightly different order, namely the United States, Germany, Belgium, China and the Netherlands.

The potential for the development of the industry and the expansion of sales of medical and pharmaceutical products on international markets depends on the harmonisation of norms and standards. Despite some progress in this area in recent years, this process has been slow. There are still different regulations in different countries, which affects the possibilities of international cooperation.

A comparison of the position of Poland and Japan in global trade in medical and pharmaceutical goods shows that both countries rank relatively high as both exporters and importers. Japan ranks 6th as a global importer and 12th as a global exporter of these products. According to WTO estimates, imports of medical and pharmaceutical products to Japan totalled around USD 70 billion in 2022, which was around 25% above the pre-pandemic level. The most important and fastest-growing group of medical and pharmaceutical industry products in Japanese imports of this product group were pharmaceuticals, which accounted for around 57% of total imports of products in this industry in 2022. Another important product group in Japanese imports of this industry was medical devices (about 19% of the industry's imports), including one third of orthopaedic devices.

Japanese exports of medical and pharmaceutical industry products are more than half lower than imports of this industry (about USD 30 bn in 2022), but they were gradually increasing in 2019–2022. In 2022, these exports were about 10% higher than in 2019. Japan's main export items in this industry are medical devices and other medical technology products (almost 40% of the industry's exports in 2022), pharmaceuticals (25%) and personal protective equipment (24%).

According to the WTO [2023], Poland also ranks high in international trade in the medical and pharmaceutical industry - 16th in imports and 20th in exports, but much lower than Japan. In 2022, Polish imports in this industry totalled USD 10 billion, an increase of one third since 2019. Polish exports in the medical and pharmaceutical industry also grew at the same pace in the period 2019–2022, reaching USD 5.6 billion in 2022. The most important items of Polish exports in this industry are pharmaceuticals (33% in 2022 with an upward trend), medical devices (27%), including orthopaedic devices (with a share of 11% in total exports of the medical and pharmaceutical industry) and personal protective equipment (24%). Polish imports in this sector are also dominated by pharmaceuticals (over 55% of imports) and personal protective equipment (23%). Medical devices accounted for around 13% of Polish imports in this sector in 2022, although the share decreased slightly compared to 2019.

The dominance of pharmaceuticals in the global trade of the industry's products and in the trade of both Poland and Japan prompts us to characterise the trade in these products in more detail. Interesting conclusions can be drawn from the analysis of global value chains in the pharmaceutical industry.This analysis is based on indicators that characterise the structure of global production of pharmaceutical products, employment, wages, international trade in pharmaceuticals and intellectual property in the industry, taking into account pricing trends.

The global production and trading centres of the pharmaceutical industry that specialise in high value-added goods are: the United States, Switzerland and Germany.

Poland, like China, India, Mexico and Hungary, is an important exporter of pharmaceutical products and uses the low production costs as a competitive factor. However, these countries are not production centres, and a characteristic feature of exports is the high proportion of foreign value added in the exported pharmaceutical products. Ireland, Israel, Singapore, Austria, Canada, Italy and Spain lie between the centre and the periphery, as they are strong exporters and importers of pharmaceutical products with a medium share of foreign value added in their exports and benefit from surpluses in intellectual property disposal fees. Japan, on the other hand, has a different structure of international relations in the area of trade with pharmaceutical products.

On the one hand, Japan is a country with a high proportion of domestic value added in its exports; on the other hand, it imports relatively more expensive pharmaceutical products and produces and exports less, focusing on those that belong to the cheaper group. Therefore, Japan acts as a sales market for foreign pharmaceuticals to a greater extent than their suppliers.]. As the survey research shows, the most important factors for the competitiveness of pharmaceutical companies are human capital and government policies related to this industry.

The above remarks on global trade in medical and pharmaceutical industry products point to specific areas where the potential for Polish-Japanese cooperation in this industry can be sought. An analysis of the volume of bilateral Polish-Japanese trade in goods from this sector will make it possible to identify current trends and opportunities for intensifying cooperation in this area. The detailed analysis will therefore cover pharmaceuticals and medical devices, including orthopaedic devices, which play an important role both in Polish exports in this sector and in Japanese imports.

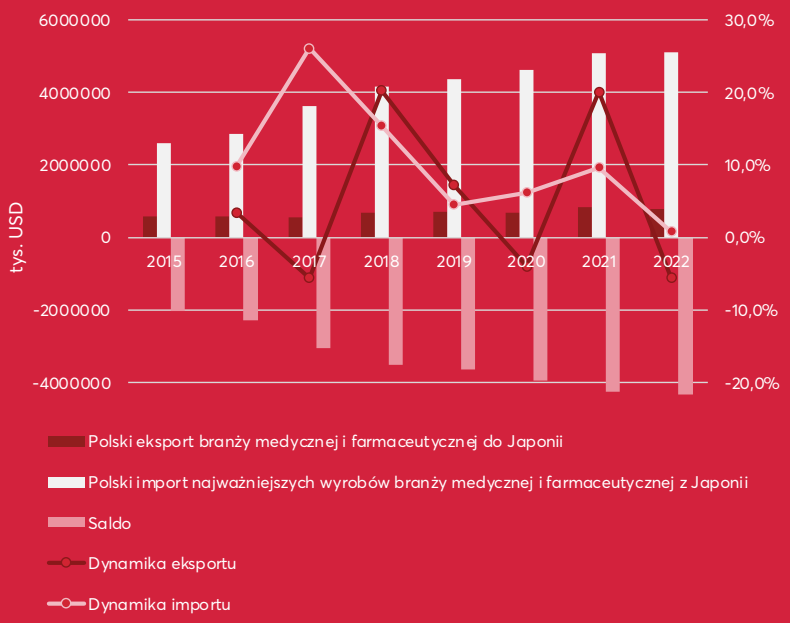
According to calculations based on data from the International Trade Center, the share of medical and pharmaceutical industry products in Polish exports to Japan increased from 1.8% to 4.5% in the period 2015–2023. In the case of Polish imports from Japan, the share of these products fluctuated around 2.5% and fell slightly in the period analysed.

The most important product groups in the medical and pharmaceutical industry – shares of Polish exports to Japan and Polish imports from Japan (%)

HS code	Name	Share in Polish exports to Japan			Share in Polish imports from Japan		
		2015	2019	2022	2015	2019	2022
'30	Pharmaceuticals	0.3%	0.5%	0.4%	0.6%	0.4%	0.8%
'9018	Medical, surgical, dental or veterinary instruments and appliances	1.3%	0.8%	0.9%	2.1%	1.3%	1.1%
,9021	Orthopaedic appliances, including crutches, surgical belts and trusses; fracture splints and other	0.2%	0.7%	3.1%	0.2%	0.0%	0.1%
	TOTAL	1.8%	2.0%	4.5%	2.9%	1.7%	1.9%

Source: study based on data of the International Trade Center (ITC TRADE MAP), accessed on: 18.06.2024.

Bilateral Polish-Japanese trade in key products of the medical and pharmaceutical industry (left axis: value in USD thousands; right axis: % change), 2015–2022



Note: the list includes three main groups of medical and pharmaceutical devices with codes HS30 (pharmaceuticals), HS9018 (medical, surgical, dental or veterinary instruments and appliances), HS9021 (orthopaedic appliances, including crutches, surgical belts and trusses; splints, etc.).

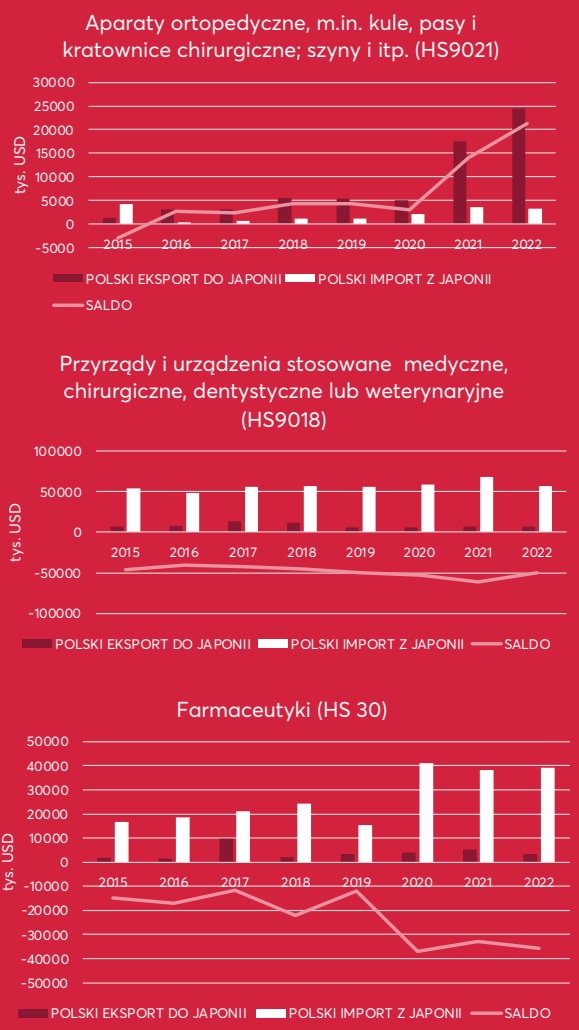
Source: study based on data of the International Trade Center (ITC TRADE MAP), accessed on: 18.06.2024.

A more detailed comparison of Polish imports from (and exports to) Japan in relation to the most important groups of medical and pharmaceutical products shows the leading trends in bilateral trade in these goods.First, the gradual increase in Polish exports of the industry's products to Japan from USD 571 million to around USD 830 million should be emphasised. However, this growth slowed down between 2015 and 2021. In 2022, on the other hand, the value of exports from this sector fell slightly to USD 784 million. The development of exports varied for the different product groups that make up the industry (. Second, Polish imports from Japan increased over the entire period analysed, from USD 2,613 million in 2015 to USD 5,119 million in 2022. As with imports, the growth gradually weakened. Third, Poland's trade deficit in trade in medical and pharmaceutical products has widened due to the significant imbalance between Polish exports of these products to Japan and their imports from Japan to Poland.

Among the medical and pharmaceutical products exported by Poland, the most important item in 2022 were orthopaedic appliances (HS9021). Exports of this product group increased sharply from USD 1,346,000 in 2015 to USD 24,462,000 in 2022 and the share of total Polish exports to Japan increased from 0.2% to 3.1% in the period 2015–2022.. The second important product group in Polish exports to Japan are medical, surgical, dental or veterinary instruments and appliances, but their share in total Polish exports to Japan decreased from 1.3% in 2015 to 0.9% in 2022. The trends in export value varied over the period 2015-2022. Polish exports of these products increased rapidly in the period 2015–2017 from USD 7,156,000 to USD 12,002,000 and after a sharp decline by more than half in 2018 to the level of USD 5,692,000 gradually increased to USD 7,314,000 in 2022.

Similar trends in changes in the value of Poland's exports to Japan concern the third product group in the medical and pharmaceutical industry – pharmaceuticals. This product group had a relatively stable share in Polish exports 0.3–0.5%, but the trends in changes in export value varied significantly in the years 2015–2022. Polish exports of pharmaceuticals increased more than fourfold in 2015–2017, from USD 1,731,000 to USD 9,563,000, and then, after the fluctuations in 2018–2021, reached the level of USD 3,863,000 in 2022.

Trade between Poland and Japan in key products of the medical and pharmaceutical industry, 2015-2022 (in USD thousands)



Source: study based on data of the International Trade Center (ITC TRADE MAP), accessed on: 18.06.2024.

The most important of the three analysed product groups in the Polish medical and pharmaceutical industry's imports from Japan are medical, surgical, dental or veterinary instruments and appliances. However, their share in bilateral imports decreased from 2.1% in 2015 to 1.1% in 2022.Imports from Japan to Poland totalled USD 57 million in 2022, up from USD 53.7 million in 2015.

Pharmaceuticals are the second product group in the medical and pharmaceutical industry in terms of the value of Polish imports from Japan.Between 2015 and 2022, these imports more than doubled from USD 16.6 million to USD 39.2 million. The result of the faster growth rate of pharmaceutical imports from Japan compared to Polish exports to this market was a growing trade deficit in this product group.

Orthopaedic devices are the third most important product group in the medical and pharmaceutical industry, which is of crucial importance for Polish-Japanese bilateral trade. As mentioned above, this is the most important group in Polish exports of the industry to Japan, while its weight in imports from Japan to Poland is relatively low (about USD 3–4 million). As a result, Poland has a significant and growing surplus in this product group in bilateral trade with Japan.

The above analysis of previous trends in Poland's bilateral trade with Japan in medical and pharmaceutical goods seems to indicate that the greatest potential for the development of Poland's cooperation with Japan in this sector can be seen in Polish exports of orthopaedic devices and trade in pharmaceuticals. This is indicated not only by the relatively large shares of these product groups in mutual trade, but also by the growing dynamism of this trade. An additional argument in favour of the potential in trade with orthopaedic devices with Japan is Japan's large and growing demand for these products (cf. the comments on the importance of orthopaedic devices in Japanese imports) and the ageing of the Japanese population. The latter factor also applies to Poland and will also determine the growing demand for all industrial products in both countries, especially for pharmaceuticals.

A directory of Polish medical and pharmaceutical companies that are present on the Japanese market or have the potential to expand there

#	Company	Production structure	Exports – geographical directions	Representative offices abroad / other forms of presence on a foreign market
Leading pharmaceutical companies operating on the Polish market of medicines and active substances belonging to the Polish Association of Employers of the Pharmaceutical Industry (PZPPF)				
1	**Adamed Pharma S.A.** (Pieńków, Mazowieckie Province, Poland) A Polish company founded in 1986 Share capital PLN 718.4 million	500 Stock Keeping Unit (SKU) products, prescription medicines (RX) (cardiology, oncology, diabetology, pulmonology, other therapeutic groups), over-the-counter (OTC) medicines: food supplements, dermocosmetics, medical devices (eye drops). Licence sales. EU-GMP (Good Manufacturing Practice) certificate	78 countries (Europe, Middle East, Asia, Africa, Latin America, Oceania)	Spain, Russia, Czech Republic, Vietnam, Italy, Kazakhstan, Uzbekistan and Slovakia, Ukraine
2	**Biofarm Sp. z o.o.** (Poznań, Poland). A Polish company founded in 1988	180 SKU products, prescription drugs (RX), over-the-counter (OTC) drugs, food supplements, cosmetics, EU-GMP (Good Manufacturing Practice) certificate	Austria, Spain, Malta, Portugal, Switzerland, United Kingdom, Italy, Ukraine, Sweden, Albania, Croatia, Cyprus, Greece, Kosovo, Serbia, Panama, Chile, Ecuador, Colombia, Iraq, China, Vietnam, Kazakhstan, Uzbekistan	Abroad: Implementation of activities related to establishing long-term cooperation (distribution, in/out licences).
3	**Egis Group** (Budapest, Hungary). Subsidiary of the Servier Group. ODDZIAŁ EGIS POLSKA SP. Z O.O.	Prescription (RX) medicines, cardiology, oncology, gynecology, dermatology, gastroenterology, medicines, other therapeutic groups, over-the-counter (OTC) medicines Treatment of hypertension and general cardiovascular diseases	Egis products are available in 100 countries through a network of subsidiaries, representative offices and partners	Subsidiaries have been established in 17 countries
4	**Gedeon Richter Polska Sp. z o.o.**, Grodzisk Mazowiecki, Mazowieckie Province, Poland The company is owned by the foreign company Gedeon Richter.	Prescription (RX) medicines: cardiology, oncology, diabetology, neurology, psychiatry, infectious diseases, other therapeutic groups, over-the-counter (OTC) medicines, GMP (Good Manufacturing Practice) certificate	Gideon Richter is a global, innovative pharmaceutical concern with a presence in over 100 countries	The parent company Gedeon Richter cooperates with partners from over 100 countries (including Japan, China, USA). Present in Poland since 1994

5	**Glenmark Pharmaceuticals Sp. z o.o.** Warsaw, Poland. The company is owned by the foreign entity.	Prescription (RX) medicines: psychiatry, neurology, orthopaedics and dermatology, allergology, pulmonology, over-the-counter (OTC) medicines: food supplements, dermocosmetics. GMP (Good Manufacturing Practice) certificate	Glenmark Pharmaceuticals sells products in over 80 countries.	The company has offices in 30 countries (in Poland since 2008.)
6	**Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o.** Zakroczym near Warsaw, Poland. A Polish company Net turnover – PLN 268 million (2021)	80 products. Prescription drugs (RX) Psychiatry, urology, pulmonology, cardiology, dermatology. Over-the-counter (OTC) medicines, food supplements, medical devices, cosmetics. GMP (Good Manufacturing Practice) certificate	Most of the production is destined for the domestic market. Some of the products are sold on foreign markets.	LEK-AM is making great efforts to expand its export business
7	**Lek (a Sandoz Company) LEK S.A.** (Sandoz group, part of the Novartis group) Stryków, Łódź Province, Poland	Lek S.A. Manufacturing Plant. Prescription (RX) medicines: painkillers and anti-inflammatory drugs, drugs used to treat diabetes and vascular hypertension. Over-the-counter (OTC) medicines, cosmetics. GMP (Good Manufacturing Practice) certificate	Sandoz sells medicines in 140 countries. The medicines produced in Poland by LEK SA are sold in 60 countries	Sandoz has 30 production plants worldwide
8	**Zakłady Farmaceutyczne POLPHARMA S.A.** Starogard Gdański, Poland Share capital: PLN 100 million A Polish company Total turnover: PLN 3,996.3 million	800 Stock Keeping Unit (SKU) products Prescription (RX) medicines: cardiology, neurology, ophthalmology, gastroenterology, gynecology. Inpatient medicines. Over-the-counter (OTC) medicines, cosmetics. Food supplements, cosmetics and medical devices. Producer of APIs for the manufacture of finished dosage forms. GMP (Good Manufacturing Practice) certificate.	Products of Polpharma S.A. are exported to 30 countries (Central and Eastern Europe, Central Asia). APIs are available in more than 60 countries. They are exported to the USA, Japan and Korea, among other countries	Polphrma S.A. engages in the B2C and B2B sale of products on foreign markets and in collaboration with local distributors.
9	**Polpharma Biologics S.A**. Duchnice, Mazowieckie Province, Poland, a Polish company. In 2013, a research and development centre is established in Gdańsk as part of Polpharma S.A., which becomes an independent company in 2019 – a spin-off from Polpharma	Development of biosimilars with significant market potential (Polpharma Biologics 1). Biosimilars are drugs that are developed on the basis of an already known active ingredient of the original preparation on the market and improve patient access to therapy and reduce its costs (Polpharma Biologics 2). For example, the biosimilar Tyruko produced by Polpharma Biologics was authorised for the treatment of relapsing-remitting multiple sclerosis (RRMS) (Polpharma Biologics 5). GMP (Good Manufacturing Practice) certificate	The company has a broad portfolio of biosimilars that can be used in many therapeutic areas. Polpharma Biologics S.A. works with the world's largest foreign biotechnology companies.	In 2016, the company began a collaboration with the Dutch biotechnology company Bioceros. In 2019, contract the commercialisation of biosimilars was concluded with Sandoz and the US company Coherus. In 2021, Polpharma signed contract with Teva for the commercialisation of a biosimilar on the European markets and in Canada

10	**Tarchomińskie Zakłady Farmaceutyczne Polfa S.A.** (Polfa Tarchomin) Head office: Warsaw, Poland	Polfa Tarchomin produces drugs in four therapeutic classes: antibiotics and tuberculosis, human insulins, psychotropic drugs and dermatics. The company manufactures 50 products in over 120 different forms. IT specialises in the production of prescription medicines (RX) for hospitals. Polfa Tarchomin is one of the most important manufacturers of injectable antibiotics, with a 48% share of the hospital market. The company is also an API manufacturer. Polfa Tarchomin manufactures over-the-counter medicines, medical devices, dermocosmetics, food supplements, disinfectants and medical masks and has a GMP (Good Manufacturing Practise) certificate.	The company mainly produces medicines for the domestic market, with exports accounting for 17% of production	Polfa Tarchomin utilises various models of cooperation in export, including representative offices, retail chains, distributors, agents
11	**Vipharm S.A.** Head office: Ożarów Mazowiecki, Mazowieckie Province, Poland A Polish pharmaceutical company founded in 1998.	Medicines manufactured by Vipharm S.A. are used in oncology, palliative care, hematology, diabetology, neurology and psychiatry. GMP (Good Manufacturing Practice) certificate	Vipharm S.A. has been present in the Czech Republic, Slovakia, Hungary and Germany since 2008.	Vipharm has its branches in the Czech Republic, Slovakia, Hungary and Germany.
12	**Servier Polska Sp. z o.o.** Warsaw, Poland A foreign company The Servier Group in Poland comprises the following companies: Servier Polska sp. z o.o. (research and development activities, marketing services), Servier Polska Services sp. z o.o. (distribution activities, accounting, purchasing services) and Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Servier's fifth largest production facility in the world, based in Warsaw.	Servier Polska Sp. z o.o. conducts research in the field of new medical technologies. The Anpharm Przedsiębiorstwo Farmaceutyczne S.A. production facility manufactures drugs for the treatment of high blood pressure, coronary heart disease, heart failure, type 2 diabetes and depression, as well as cardiological drugs. GMP (Good Manufacturing Practice) certificate.	50% of the medicines produced in Poland are exported to 21 countries, mainly to EU countries, including: France, Lithuania, Latvia, Estonia, Slovakia, Croatia, the Czech Republic, Slovenia, Romania, Italy, Bulgaria, Austria, Hungary, Greece, Spain, Malta and Cyprus, as well as Burma, Serbia, Ireland and the United Kingdom.	Servier, which is headquartered in France, is also present in more than 150 countries worldwide (3). The sale of pharmaceuticals in certain regions of the world is carried out by four subsidiaries: EGIS (Central and Eastern Europe), Pharlab (Brazil), Swipha (Nigeria) and Biogaran, the market leader in the generics segment in France.

13	**Wytwórnia Surowic i Szczepionek BIOMED S.A.** Head office: Cracow, Poland.	Instytut Biotechnologii Surowic i Szczepionek (Institute of Biotechnology of Serums and Vaccines) BIOMED S.A. is an expert in the field of vaccines and probiotics. A probiotic contains live microorganisms that have a positive effect on the microflora of the patient's organism. Vaccines protect the population against infectious diseases. Immunostimulating products are created. IBSS BIOMED S.A. products contain probiotic bacterial strains that are used in the prevention and treatment of many diseases. Medicinal products, food supplements, medical devices, cosmetics are offered. The company has a GMP (Good Manufacturing Practice) certificate.	IBSS BIOMED S.A. has been selling its products in dozens of countries in Europe, Asia, Africa and Australia for over 10 years.	The company cooperates with foreign partners in the registration, promotion and distribution of products.
14	**Teva Pharmaceuticals Polska Sp. z o.o.** Head office: Warsaw, Poland	Teva's factories produce prescription drugs, over-the-counter drugs and dietary supplements. Around 500 products are manufactured, including painkillers, anti-inflammatory drugs, anti-infectives used for cardiovascular diseases, diseases of the central nervous system, transplantology, oncology and dermatology. The company has a GMP (Good Manufacturing Practice) certificate.	Teva Pharmaceuticals Polska Sp. z o.o. exports medicines to the EU. 65% of the Krakow plant's production is exported. Teva Pharmaceutical Industries Ltd. supplies medicines and active ingredients to markets in more than 60 countries on various continents (North America, South America, Europe, Asia including China and Japan).	Teva Pharmaceutical Industries Ltd. operates a network of research institutes, manufacturing plants and trading companies in 30 European countries.

Pharmaceutical companies operating on the Polish market – members of the Warsaw Stock Exchange

15	**CELON PHARMA S.A.** Head office: Kiełpin/Łomianki, Mazowieckie Province, Poland	An integrated pharmaceutical company. The company's strength lies in its strong research and development facilities (two fully equipped research laboratories), where innovative drugs are developed for the treatment of cancer, neurological diseases, diabetes and other metabolic disorders. Celon Pharma S.A. is a manufacturer of inhaled medicines for asthma. The company focuses on the production and distribution of specialised generics (equivalent products). It has a GMP (Good Manufacturing Practice) certificate.	Scandinavian markets (Denmark, Sweden, Norway). Projected increase in exports of medicines to the German and UK markets. Increasing export sales (China, Mexico, Saudi Arabia, South Africa).	International partnership in the implementation of clinical trial projects. Outside of Poland, medicines are commercialised through business partners such as Glenmark, Viatris (formerly Mylan) and Genericon.

16	**Synthaverse S.A.** Head office: Lublin, Poland (formerly Biomed Lublin Wytwórnia Surowic i Szczepionek). The company has been listed on the primary market of the WSE since 2015.	A Polish pharmaceutical company. It manufactures 60 products in various ranges. Specialised in the production of serums and vaccines, immunotherapy (treatment of bladder cancer). Synthaverse also manufactures medical preparations (prescription and over-the-counter drugs), medical devices and laboratory reagents (used in biochemical and medical laboratories). The company is also the developer of a tuberculosis vaccine that is used to immunise all newborns in the country and is widely used around the world.	Synthaverse's products are supplied to more than 50 countries.	The company works with business partners in over 20 countries in Europe, Asia and South America.
17	**BIOTON S.A.** Head office: ul. Starościńska 5, Warsaw, Poland. Contact: BIOTON S.A. Zakłady Podukcyjne Macierzysz, ul. Poznańska 12 Ożarów Mazowiecki	Bioton manufactures and distributes medicines and biotechnology products. The company produces clinically important and state-of-the-art drugs, including recombinant human insulin and its pharmaceutical forms, human growth hormone and various antibiotics. The BIOTON plant in Macierzysz near Warsaw is one of the most modern biotechnology facilities in the world. This is where insulin is produced – both the active ingredient and the finished dosage forms. The company has a GMP (Good Manufacturing Practice) certificate.	BIOTON S.A. registers its products in many countries around the world. The company's insulins are available in over 20 countries in Europe, Latin America, Asia and Africa.	Sales outside Poland are made on the basis of co-operation agreements and purchase contracts concluded with foreign and domestic partners.
18	**Mabion S.A.** Head office: Konstantynów Łódzki, Poland Mabion S.A. debuted on the primary market of the Warsaw Stock Exchange on 23 April 2013.	The company specialises in the production of sterile biotechnology products. Mabion S.A. is a Polish biotechnology company established to commercialise the latest generation of biotechnological drugs based on humanised monoclonal antibodies. This technology enables the production of targeted drugs that act selectively on cancer cells and offer improved efficacy and reduced toxicity of therapy. Mabion Sp. z o.o. was founded by six domestic pharmaceutical companies: Polfarmex S.A., Instytut Biotechnologii Surowic i Szczepionek BIOMED S.A., CelonPharma Sp. z o.o, Genexo Sp. z o.o., Biotech Consulting Sp. z o.o. and Bio-Centrum Sp. z o.o.	Mabion Sp. z o.o. cooperates with Novavax, an US biotechnology company. Mabion will conduct stability studies on intermediates and substances produced and used in the manufacturing process of the SARS-CoV-2 rS agent of the Nuvaxovid vaccine.	The company expands international cooperation in areas affecting the success of activities of the CDMO (Contract Development and Manufacturing Organization)

Companies operating on the Polish market, members of the Warsaw Stock Exchange in the health care sector's group "medical equipment and supplies

19	**Mercator Medical S.A.** Cracow, Poland. The company's manufacturing facility is located in Thailand.	Mercator Medical S.A. manufactures disposable medical devices (gloves), medical dressings and non-woven protective products, e.g. medical clothing and surgical drapes	The company is active in more than 60 countries and offers around 120 products: both its own and those of other renowned international brands.	Subsidiaries of the company are located in 10 countries: Thailand, Ukraine, Romania, Hungary, Russia, Czech Republic, Italy, Germany, Netherlands, France
20	**SDS Optic S.A.** Lublin, Poland The company debuted on the NewConnect market on 15 March 2022	SDS Optic S.A. develops medical technologies that combine fibre optic optoelectronics (photonics), molecular biology, immunochemistry and modern medical bioengineering techniques. The company also works in the field of technologies for diagnostic devices and the monitoring of life processes in their natural state and in real time, focusing on cancer, infectious, viral, bacterial and fungal disease. The company has developed inPROBE®, the world's first fibre-optic microprobe for real-time cancer diagnosis with the first application area of HER2+ breast cancer detection.	Commercialization of inPROBE technology on a global scale	Participation in the trade fairs MEDICA2021 in Düsseldorf, Life Science Open Space 2021 conferences, European Innovation Council Summit 21. Presentation of the product and technology internationally, establishment of business relationships and outreach to potential end users.

Poland.

The Polish Investment and Trade Agency

The Polish Investment and Trade Agency's mission as a Government Agency is:

- To enable small-and medium-sized companies to reach their full potential in exporting their products and services around the world
- To support potential investors in Poland by providing comprehensive and up-to-date information services regarding legal and tax aspects, location and human capital, as well as on the available financial incentives
- To promote 'Poland as a Brand'

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