

ASSOCIATION OF PARALLEL IMPORTERS OF MEDICINAL PRODUCTS

**The impact of import on the competitive situation
on the market for medicinal products in Poland
in the years 2010-2018**

Warsaw 2019

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1. Summary

Parallel imported medicines (PI) have generated savings as high as PLN 3.1 billion (EUR 721 million¹) since 2010, i.e. over the last 9 years, including over PLN 307 million (EUR 71 million) generated by reimbursed medicinal products, and they are growing every year. In 2018, the savings exceeded PLN 532 million (EUR 123 million).

Parallel import is a form of distribution of medicinal products within the European Economic Area. Parallel importers purchase products on foreign markets where they are offered at lower prices in comparison with those offered by the original manufacturers on the Polish pharmaceutical market.

The parallel importers are subject exactly to the same legal regulations as other pharmaceutical wholesalers on the Polish market, while product repacking plants operate under the same conditions which are applicable for their manufacturers. The mode and scope of inspection is also identical. As a result, parallel imports are completely safe.

The medicinal products from the PI are not generics. They are the same medicinal products purchased from a distributor on the European market at a lower price than the one offered by the manufacturer in Poland.

A lower price implies not only savings, but also an easier access to modern therapies, as PI is the only form of competition for the medicinal products which are subject to patent protection.

Furthermore, PI medicinal products trigger price pressure by forcing the manufacturers to lower the prices for their products offered in Poland, which generates indirect savings.

The most important facts about PI in the years 2010-2018

Over 176 million *packages* were put on the market by parallel importers

Over PLN 3.1 billion (EUR 721 million) *savings (direct and indirect) for the patients*

Over PLN 307 million (EUR 71 million) *savings generated by the reimbursed medicinal products for the patients and the NHF*

Over PLN 532 million (EUR 123 million) *savings (direct and indirect) for the patients in 2018*

The market for reference medicinal products, which compete with the PI, had a value of over PLN 3.6 billion (EUR 837 million) in 2018

Over 600 medicinal products from PI are currently available in Poland

The PI has operated for over 14 years in Poland

For the purposes of this Report, the reference product means a product the documentation of which was referred to by the Registration Office for Medicinal Products while issuing a parallel import marketing authorization, or a centrally authorized product which is distributed in parallel. The price of the reference product² distributed by the manufacturer differs depending on the price strategies of the original manufacturers.

¹ The prices in PLN were translated into EUR using the 4.3 PLN/EUR exchange rate throughout in the report.

² Reference product in the context of this report is a product put on the market by the manufacturer or by its designated representative whereas a parallel imported product is put on the market by a parallel importer "in parallel" to the reference product.

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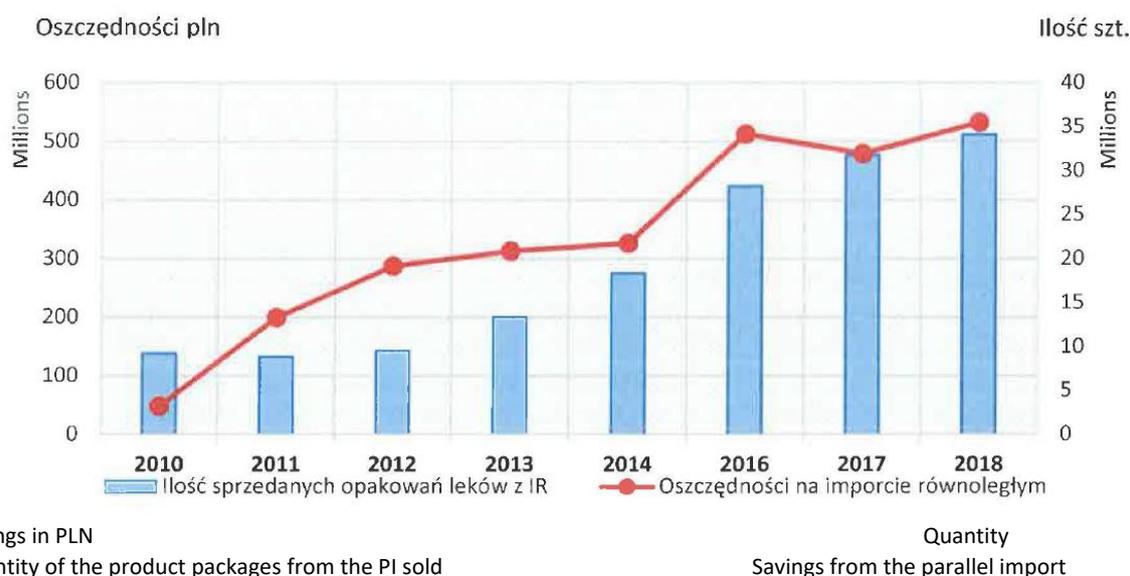
The savings generated by the parallel import on the Polish market benefit all its stakeholders: the patients, the National Health Fund and the hospital operators. The study on savings is a continuation of a study for the period covering November 2005 up until December 2009. Detailed information on the former report is available on the website of the Association of Parallel Importers of Medicinal Products: https://sirpl.org/Aktualnosci/2010-05-13-pacjenci-zaoszczedzili-prawie-300-mln-dzieki-importowi-rownoqlemu_n28.

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Table 1. Summary of savings in different segments of the market in the years 2005-2018 in EUR million.

	2005-2009	2010-2014	2015-2018	Total 2010-2018
1. Total savings	68.37	274.28	453.37	727.65
2. Medicinal products distributed to pharmacies jointly	68.02	263.67	378.09	641.77
2. a) Direct savings	16.77	51.70	134.88	186.58
2. b) Indirect savings	51.26	212.00	243.19	455.19
3. Medicinal products distributed to hospitals jointly	0.26	5.07	9.35	14.42
3. a) Direct savings	0.12	0.81	2.05	2.86
3. b) Indirect savings	0.14	4.26	7.30	11.56
4. Reimbursed medicinal products	0.12	5.51	65.95	71.47
4. a) Savings for the patient	0.09	4.95	42.40	47.35
4. b) Savings for the NHF	0.00	0.56	23.53	24.12

Figure 1. Direct and indirect savings generated by the parallel import in the years 2010-2018 in comparison with the volume of the product packages from the PI sold.



The analysed period is marked by a gradual increase in the quantity of the product packages from the parallel import sold, which generates increasing savings for the patients, hospitals and for the state budget every year (Figure 1).

2. Methodology for the calculation of savings from parallel imports in Poland

2.1. Data specification

The volume of savings from the impact of the parallel import on the pharmaceutical market was analysed based on monthly data from the IQVIA Poland National Sales Data system between January 2010 until December 2018. The analysis includes the savings for the hospitals, patients and for the National Health Fund, split as direct and indirect savings.

The analysis was performed based on the IQVIA Poland National Sales Data.

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The savings resulting from the difference in sale prices of the reimbursed parallel imports and of the reference medicinal products were calculated independently for the patient and for the public payer. Parallel imports are not generics. They are the same medicinal products purchased from the distributor in a foreign country at a lower price and not from the same company offering the same products at a higher price on the Polish market. The analysis draws on the data published on the website of the Ministry of Health – the list of the reimbursed medicinal products in the years 2012-2018 and the data published by the National Health Fund on the quantity and value of the reimbursed medicinal products sold in different months during the aforementioned period.

For the products from parallel import which had no equivalent reference medicinal products, due to different package sizes, parallel imports were matched with the reference products with a similar package size. For example, if a parallel import “X” contained 28 pills, while the reference product contained 30 pills, both products were deemed equivalent in accordance with *the Act of 28 March 2016 on amending the Act on the health-care services financed from public funds and certain other acts*, which allows for a difference of 10% in the size of the package.

The analysis was performed based on the net sale value in the wholesale distribution channel for the reference and imported medicinal products. This study was conducted at net prices, which guarantees the comparability of data in the periods when commercial parameters, including the margins and VAT, changed.

The study for the period from November 2005 until December 2009 was conducted based on the gross sale value (VAT 7%), including the fixed pharmacy margin for the medicinal products distributed to the pharmacies by estimating the value of sales to the patients.

2.2. Direct savings

The first step of the analysis of savings for the public payer and for the hospitals was to calculate the average prices of the parallel imports and of the reference medicinal products based on the monthly quantity and sale value between January 2010 until December 2018.

The average price was calculated according to the formula:

$$P_{avg} = V/Q$$

Where:

P_{avg} – average price of a products

V – monthly sale value of the reference or imported product

Q – monthly sale quantity of the reference or imported product

Direct savings were calculated based on the difference in prices of the reference and imported medicinal products. The price difference was multiplied by the quantity of the parallel imports sold.

Direct savings were calculated according to the formula:

$$S_d = (P_{ref} - P_{im}) \times Q_{im}$$

The analysis was performed based on the IQVIA Poland National Sales Data.

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Where:

S_d – direct savings

P_{ref} – price of the reference product

P_{im} – price of the product from the parallel import

Q_{im} – quantity of the product packages from the parallel import sold

In case the savings are negative (the reference product is cheaper than the product from the parallel import), the amounts decrease the total direct savings.

2.3. Indirect savings

The indirect savings are generated when manufacturers lower prices of the reference medicinal products in case they face a steady competition of parallel imports. The first step of the analysis was to establish the base price for the reference product. The base price is the price of the reference product of the month when the parallel import was made available on the pharmaceutical market for the first time.

The estimation of the indirect savings consists of the calculation of the difference between the price of the reference product in the respective month and the base price of the reference product multiplied by the quantity of the packages of the reference product sold from January 2010 up until December 2018.

The indirect savings were calculated according to the formula:

$$S_i = (P_B - P_{ref}) \times Q_{ref}$$

Where:

S_i – indirect savings

P_B – base price of the reference product

P_{ref} – price of the reference product

Q_{ref} – quantity of the packages of the reference product sold

3. Savings for the patient and for the public payer – reimbursed medicinal products – methodology

3.1. Savings for the patient

In case the reimbursed parallel imports are purchased, the savings for the patient result from the difference in the co-payment of the recipient of the service (patient) for the reference product and for the product from the parallel import multiplied by the quantity of the reimbursed packages from the parallel import.

The savings for the patient were calculated according to the formula:

$$S_{patient} = (D_{ref} - D_{im}) \times Q_{im}$$

Where:

The analysis was performed based on the IQVIA Poland National Sales Data.

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S_{patient} – savings for the patient

D_{ref} – surcharge of the recipient of the service for the reference product

D_{im} – surcharge of the recipient of the service for the imported product

Q_{im} – quantity of the reimbursed packages from the parallel import

3.2. Savings for the National Health Fund

In case the reimbursed parallel imports are purchased, the savings for the National Health Fund were calculated based on the difference in the financing threshold (surcharge of the NHF) for the reference product and for the product from the parallel import multiplied by the reimbursed packages of the imported product.

The savings for the NHF were calculated according to the formula:

$$S_{\text{NHF}} = (F_{\text{ref}} - F_{\text{im}}) \times Q_{\text{im}}$$

Where:

S_{NHF} – savings for the NHF

F_{ref} – financing threshold for the reference product

F_{im} – financing threshold for the imported product

Q_{im} – quantity of the reimbursed packages from the parallel import

4. Results

The sale value of the parallel imports which have been distributed to pharmacies and hospitals over the last 9 years is gradually increasing. In the analysed period, the market share by value of sales of the parallel imported medicinal products distributed to the pharmacies over the reference medicinal products amounted to 8.6%, while the market share of the medicinal products distributed to the hospitals amounted to 5.6%. *Table 2* and *Table 3* contain the detailed results.

4.1. Sales of parallel imports and reference medicinal products

Table 2. The sales of the reference medicinal products and of the parallel imports which were distributed to the pharmacies in the years 2010-2018 (in EUR).

Medicinal products distributed to the pharmacies

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sale value – reference medicinal products	882,779,668	892,580,374	863,912,044	859,737,220	794,334,581	805,676,979	811,209,755	811,466,987	804,089,119
Sale value – medicinal products from the PI	47,554,622	40,432,144	43,388,448	56,973,081	68,504,943	84,678,583	95,530,776	99,664,454	102,743,557
Quantity of the sold packages – reference medicinal products	48,669,421	49,469,841	47,138,184	46,949,190	45,652,625	45,287,491	46,230,130	45,360,095	44,250,224
Quantity of the sold packages – medicinal products from the PI	2,135,882	2,019,497	2,177,353	3,063,367	4,215,995	5,476,825	6,471,694	7,279,488	7,833,917
Sale value – medicinal products from the PI / Sale value – reference product %	5.40%	4.50%	5.00%	6.60%	8.60%	10.50%	11.80%	12.30%	12.80%
Quantity of the sold packages – medicinal products from the PI / Quantity of the sold packages – reference product %	4.40%	4.10%	4.60%	6.50%	9.20%	12.10%	14.00%	16.00%	17.70%

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Table 3. The sales of the reference medicinal products and of the parallel imports which were distributed to the hospitals in the years 2010-2018 (in EUR).

Medicinal products distributed to the hospitals

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sale value – reference medicinal products	69,183,984	50,021,755	42,469,517	43,906,310	46,046,570	50,481,853	41,482,217	36,956,219	37,333,708
Sale value – medicinal products from the PI	1,245,875	2,423,414	1,601,536	1,425,015	2,534,327	2,971,563	3,106,356	3,275,902	3,451,435
Quantity of the sold packages – reference medicinal products	771,313	737,699	687,002	704,739	716,048	747,135	748,782	743,045	740,829
Quantity of the sold packages – medicinal products from the PI	14,788	36,058	47,082	47,042	53,550	51,724	63,119	71,178	67,993
Sale value – medicinal products from the PI/ Sale value – reference product %	1.8%	4.8%	3.8%	3.2%	5.5%	5.9%	7.5%	8.9%	9.2%
Quantity of the sold packages – medicinal products from the PI/ Quantity of the sold packages – reference product %	1.9%	4.9%	6.9%	6.7%	7.5%	6.9%	8.4%	9.6%	9.2%

The analysis was performed based on the IQVIA Poland National Sales Data.

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4.2. Direct savings

Table 4. Direct savings from the sales of the parallel imports which were distributed to the pharmacies in the years 2010-2018 (in EUR).

Medicinal products distributed to the pharmacies

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Sale quantity – reference medicinal products	48,669,421	49,469,841	47,138,184	46,949,190	45,652,625	45,299,897	46,230,130	45,360,095	44,250,224	419,007,201
Sale quantity – medicinal products from the PI	2,135,882	2,019,497	2,177,353	3,063,367	4,215,995	5,476,825	6,471,694	7,279,488	7,833,917	40,674,019
Sale value – reference medicinal products	882,779,668	892,580,374	863,912,044	859,737,220	794,334,581	805,676,979	811,209,755	811,466,987	804,089,119	7,525,786,727
Sale value – medicinal products from the PI	47,554,622	40,432,144	43,388,448	56,973,081	68,504,943	84,678,583	95,530,776	99,664,454	102,743,557	639,470,607
Direct savings	5,820,900	6,775,483	8,556,520	12,515,904	18,023,428	25,948,389	30,622,328	36,682,526	41,635,804	186,581,282
Direct savings/ Sale value – reference medicinal products %	0.7%	0.8%	1.0%	1.5%	2.3%	3.2%	3.8%	4.5%	5.2%	2.5%

The analysis was performed based on the IQVIA Poland National Sales Data.

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Table 5. Direct savings from the sales of the parallel imports which were distributed to the hospitals in the years 2010-2018 (in EUR).

Medicinal products distributed to the hospitals

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Sale quantity – reference medicinal products	771,313	737,699	687,002	704,739	716,048	747,135	748,782	743,045	740,829	6,596,591
Sale quantity – medicinal products from the PI	14,788	36,058	47,082	47,042	53,550	51,724	63,119	71,178	67,993	452,534
Sale value – reference medicinal products	69,183,984	50,021,755	42,469,517	43,906,310	46,046,570	50,481,853	41,482,217	36,956,219	37,333,708	417,882,133
Sale value – medicinal products from the PI	1,245,875	2,423,414	1,601,536	1,425,015	2,534,327	2,971,563	3,106,356	3,275,902	3,451,435	22,035,424
Direct savings	48,164	155,326	42,029	95,886	482,735	353,720	506,234	555,875	625,360	2,865,328
Direct savings/ Sale value – reference medicinal products %	1.9%	4.9%	6.9%	6.7%	7.5%	6.9%	8.4%	9.6%	9.2%	6.9%

Table 6. Total direct savings generated on the pharmaceutical market thanks to the parallel import in the years 2010-2018 (in EUR).

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Direct savings from the medicinal products distributed to hospitals	48,164	155,326	42,029	95,886	482,735	353,720	506,234	555,875	625,360	2,865,328
Direct savings from the medicinal products distributed to pharmacies	5,820,900	6,775,483	8,556,520	12,515,904	18,023,428	25,948,389	30,622,328	36,682,526	41,635,804	186,581,282
TOTAL	5,869,064	6,930,808	8,598,548	12,611,791	18,506,163	26,477,400	31,128,562	37,238,401	42,261,164	189,446,610

The analysis was performed based on the IQVIA Poland National Sales Data.

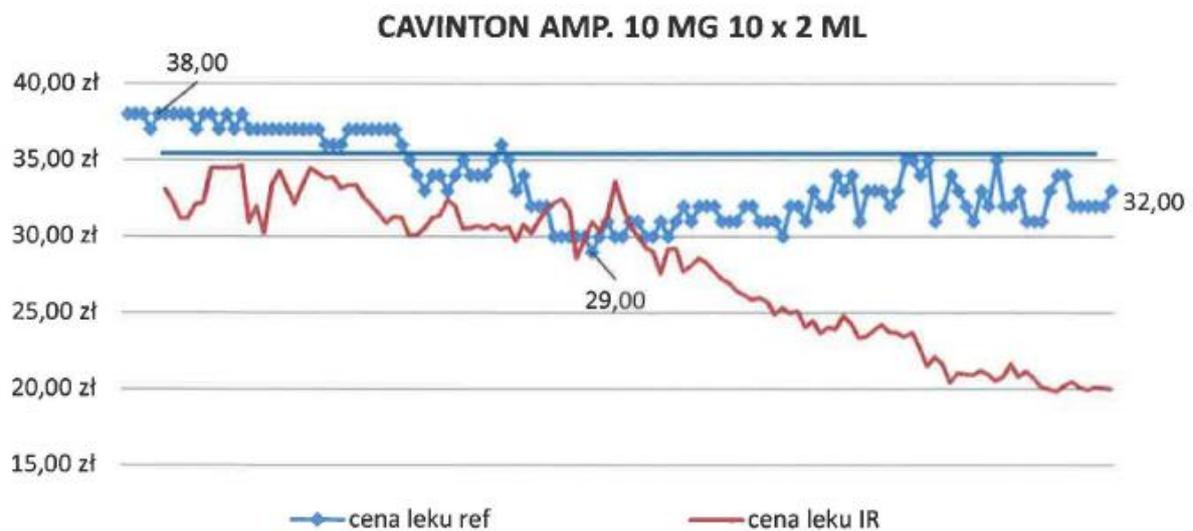
4.3. Indirect savings

The indirect savings result from the price pressure, i.e. the fact that manufacturers decrease prices in case more affordable parallel imports are put on the market.

The analysis demonstrated that the indirect savings related to the medicinal products distributed to pharmacies and hospital amount to a total of PLN 2,006.98 million (EUR 466,74 million). The savings from the price pressure on the medicinal products distributed to the hospitals amount to PLN 49.69 million (EUR 11,55 million). However, most of the indirect savings are generated by the market for the pharmacies – the sale value of the Tx and OTC medicinal products to the pharmacies amounts to PLN 1,957 million (EUR 455 million) (Table 9).

The figures below show the products distributed to the hospitals and pharmacies by a clearly noticeable price pressure.

Figure 2. Prices of the product distributed to hospital Cavinton 10 mg 10 amp. x 2ml – the reference product and the product from the PI – and the indirect savings resulting from the price pressure.



Price of the reference product

Price of the product from the parallel import

The reference product Cavinton 10 mg 10 amp. x 2ml was sold at an average price of PLN 38 to hospitals. Upon putting a cheaper competitive product from the parallel import onto the market, the prices started falling dawn gradually while generating indirect savings (blue line). The lowest price of the reference product amounted to PLN 29 during the analysed 9 years. The availability of the product from the PI triggered a decrease in the price by PLN 9, i.e. 24%. Fluctuations in the price of the reference product are presented on *Figure 2*.

Table 7. Indirect savings related to the medicinal products distributed to the pharmacies due to the existence of the parallel import in the years 2010-2018 (in EUR).

Medicinal products distributed to the pharmacies

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Indirect savings	5,475,768	39,338,327	57,253,624	56,685,440	53,236,490	60,416,085	74,900,219	52,646,350	55,230,089	455,182,393
Sale quantity – reference medicinal products	48,669,421	49,469,841	47,138,184	46,949,190	45,652,625	45,287,491	46,230,130	45,360,095	44,250,224	419,007,201
Sale quantity – medicinal products from the PI	2,135,882	2,019,497	2,177,353	3,063,367	4,221,821	5,502,540	6,514,560	7,323,038	7,872,471	40,830,530
Sale value – reference medicinal products	882,779,668	892,580,374	863,912,044	859,737,220	794,334,581	805,676,979	811,209,755	811,466,987	804,089,119	7,525,786,727
Sale value – medicinal products from the PI	47,554,622	40,432,144	43,388,448	56,973,081	68,563,201	84,934,209	95,886,364	100,020,474	103,010,373	640,762,916
Indirect savings/ Sale value – reference medicinal products %	0.62%	4.41%	6.63%	6.59%	6.70%	7.50%	9.23%	6.49%	6.87%	6.05%

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Table 8. Indirect savings related to the medicinal products distributed to the hospitals due to the existence of the parallel import in the years 2010-2018 (in EUR).

Medicinal products distributed to the hospitals

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Indirect savings	137,217	351,110	816,808	1,279,854	1,659,627	1,866,087	1,886,634	1,962,316	1,596,692	11,556,345
Sale quantity – reference medicinal products	771,313	737,699	687,002	704,739	716,048	747,135	748,782	743,045	740,829	6,596,591
Sale quantity – medicinal products from the PI	14,788	36,058	47,082	47,042	53,550	51,724	63,119	71,178	67,993	452,534
Sale value – reference medicinal products	69,183,984	50,021,755	42,469,517	43,906,310	46,046,570	50,481,853	41,482,217	36,956,219	37,333,708	417,882,133
Sale value – medicinal products from the PI	1,245,875	2,423,414	1,601,536	1,425,015	2,534,327	2,971,563	3,106,356	3,275,902	3,451,435	22,035,424
Indirect savings/ Sale value – reference medicinal products %	0.20%	0.70%	1.92%	2.91%	3.60%	3.70%	4.55%	5.31%	4.28%	2.77%

Table 9. Summary of the indirect savings generated in the years 2010-2018.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
Indirect savings – medicinal products distributed to the hospitals	137,217	351,110	816,808	1,279,854	1,659,627	1,866,087	1,886,634	1,962,316	1,596,692	11,556,345
Indirect savings – medicinal products distributed to the pharmacies	5,475,768	39,338,327	57,253,624	56,685,440	53,236,490	60,416,085	74,900,219	52,646,350	55,230,089	455,182,393
TOTAL	5,612,985	39,689,437	58,070,432	57,965,294	54,896,117	62,282,172	76,786,853	54,608,667	56,826,781	466,738,737

The analysis was performed based on the IQVIA Poland National Sales Data.

4.4. Reimbursed medicinal products – savings for the state and for the patient

Putting the reimbursed parallel imports onto the market brings material benefits for the patient and for the National Health Fund. The savings generated by the reimbursed parallel imports were analysed for a period from 2012, which marked the entry into force of the Act on the reimbursement of medicinal products.

In the years 2012-2018, the savings related to the reimbursed parallel imports amounted to a total of PLN 203.6 million (EUR 47,3 million) for the patients and PLN 103.7 million (EUR 24,1 million) for the National Health Fund. It is noticeable that the sales of the reimbursed parallel imports are gradually increasing, which is generating higher savings for the patients and for the state budget. The increase is unfortunately relatively low due to the provisions of the Act on the reimbursement of medicinal products which limit the quantities of the reimbursed parallel imports. Although parallel imports are equivalent to the market products which are offered by the producer at a higher price, they are treated as generics. This results in economically unjustified decisions when the public payer gives up savings below 25% of the price of the reference medicinal products and more expensive therapies are provided by pharmaceutical manufacturers in Poland instead of those cheaper ones provided by parallel importers.

Table 10 below presents detailed results of the analysis.

Table 10. Savings for the patient and for the National Health Fund from the sales of the reimbursed parallel imports (in EUR).

Reimbursed medicinal products

	2012	2013	2014	2015	2016	2017	2018	TOTAL
Sale value - medicinal products from the PI	1,713,161	8,161,588	10,311,435	19,921,535	26,876,911	37,799,673	48,445,804	153,230,108
Sale value – reference medicinal products	2,074,445,959	2,086,148,909	1,917,164,114	1,881,342,230	1,622,810,929	1,640,121,670	1,589,431,284	12,811,465,095
Sale quantity – medicinal products from the PI	111,839	522,966	730,751	1,689,259	2,560,451	3,713,473	4,383,752	13,712,491
Savings for the patient	335,584	2,323,344	2,292,172	6,915,419	7,727,651	12,355,206	15,398,914	47,348,290
Savings for the NHF	27,278	38,438	500,922	2,833,566	3,781,283	7,464,314	9,465,968	24,111,768
Total savings	362,862	2,361,782	2,793,094	9,748,984	11,508,933	19,819,520	24,864,882	71,460,057
Savings/ Sale value – reference medicinal products %	0.02%	0.11%	0.15%	0.52%	0.71%	1.21%	1.56%	0.56%

The analysis was performed based on the IQVIA Poland National Sales Data.

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**REPORT OF THE INDEPENDENT AUDITOR ON THE ASSURANCE ENGAGEMENT CONCERNING THE
REVIEW OF THE CONSISTENCY OF THE CALCULATION OF DIRECT AND INDIRECT SAVINGS
FROM THE PARALLEL IMPORT IN THE YEARS 2010-2018**

For the Management Board of the Association of Parallel Importers of Medicinal Products

Scope of the engagement

We were appointed by the Management Board of the Association of Parallel Importers of Medicinal Products (hereinafter referred to as the "APIMP") to perform an assurance engagement giving a rational assurance as to the correctness of the calculation of direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the attached report entitled "*The impact of the import on the competitive situation on the market for medicinal products in Poland in the years 2010-2018*" (hereinafter referred to as the "Report of the APIMP") in accordance with the methodology specified in Chapters 2 and 3 of the Report of the APIMP (hereinafter referred to as the "calculation basis").

The Report of the APIMP was prepared by the Management Board of the APIMP based on the market data concerning the quantity and sale value of the parallel imports and their local equivalents from pharmaceutical wholesale operators to open pharmacies and hospitals in Poland in the years 2010-2018. The market data come from the IQVIA (formerly IMS Health and Quintiles) Poland National Sales Data.

Specification of the criteria

The criteria determining the method for calculating the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the attached Report of the APIMP, were presented in the calculation basis.

Responsibility of the Management Board of the APIMP

The Management Board of the APIMP is responsible for the calculation of the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the attached Report of the APIMP, as well as for the internal control the Management Board of the APIMP deems necessary to ensure that the Report of the APIMP is free from any material misstatement caused by a fraud or error.

Responsibility of the Independent Auditor

Our task was to audit the consistency of the calculation of the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the Report of the APIMP, with the calculation basis. We performed the engagement in accordance with the International Standard on Assurance

Engagements 3000 (as amended) “Assurance Engagements other than Audits or Reviews of Historical Financial Information” in the version adopted by the National Council of Statutory Auditors as the National Standard on Assurance Engagements other than Audit and Review 3000 (Z).

This standard obliges us to plan and carry out such procedures to gather any information and explanations we find necessary to gain a rational assurance that the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the Report of the APIMP, were calculated correctly in accordance with the calculation basis in any and all material aspects.

The selection of procedures depends on our judgment, including our risk assessment that the calculation of the direct and indirect savings from the parallel import in the years 2010-2018 contains material misstatements caused by purposeful actions or errors. While assessing the risk, we consider the internal control related to the calculation of the direct and indirect savings from the parallel import in the years 2010-2018 to plan adequate procedures and not to express a conclusion as to the effectiveness of its operation.

While performing our engagement, we are not responsible for the actualization of the market data bases the data used for preparing the Report of the APIMP come from and for the calculation of the direct and indirect savings from the parallel import in the years 2010-2018. Our procedures are not an audit or review of the market data used for preparing the Report of the APIMP and for calculating the direct and indirect savings from the parallel import in the years 2010-2018.

Deloitte Audyt spółka z ograniczoną odpowiedzialnością sp. k. and its employees are not responsible for any decisions taken based on this Report.

Quality control requirements

We follow the provisions of Resolution No. 2040/37a/2018 of the National Council of Statutory Auditors of 3 March 2018 on the national quality control standards and we maintain a comprehensive quality control system consisting of documented policies and procedures concerning the compliance with ethical standards, professional standards and applicable legal and regulatory requirements.

Ethical and independence requirements

We follow the independence requirements and other ethical requirements specified in the Code of Ethics for Professional Accountants of the International Federation of Accountants (IFAC) in the wording included in the Handbook of the Code of Ethics for Professional Accountants, 2016 Edition, introduced by the International Ethics Standards Board for Accountants (IESBA), adopted for application by Resolution No. 2042/38/2018 of the National Council of Statutory Auditors of 3 March 2018 on the principles of professional ethics for statutory auditors.

Summary of the performed work

The assurance engagement involved the verification of the consistency of the calculation of the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the Report of the APIMP, with the calculation basis, as well as the mathematical correctness of the calculation.

We believe that the evidence we gathered during the performance of the assurance engagement are a sufficient and adequate basis for expressing our opinion.

Opinion

In our opinion, the calculation of the direct and indirect savings from the parallel import in the years 2010-2018, as indicated in the Report of the APIMP, was performed correctly in accordance with the calculation basis in any and all material aspects.

Applicable limitations

This report is for the purposes of the APIMP and is to provide relevant information under the contract. The report may be disclosed to other third parties only as a whole along with the Report of the APIMP entitled "*The impact of the import on the competitive situation on the market for medicinal products in Poland in the years 2010-2018*".

Performing the assurance engagement in the name of Deloitte Audyt spółka z ograniczoną odpowiedzialnością sp. k. – the entity operating based on the entry in the register of audit firms kept by the National Council of Statutory Auditors under number 73:

Przemysław Zawadzki
Statutory Auditor No. 11337

Warsaw, 28 November 2019

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