COMPENDIUM OF REIMBURSEMENT IN POLAND IN 2016

KRAKÓW 2017

HTA consulting

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INTRODUCTION

The Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices (hereinafter referred to as the new Reimbursement Act) introduced legislative changes to the reimbursement of medicines (and foodstuffs intended for particular nutritional uses and medical devices), significantly shaping the changes in the market. The entry into force of the new Reimbursement Act triggered a process of gathering information by HTA Consulting on the reimbursement of medicines, in the custom made database, enabling for an intuitive analysis of data regarding the reimbursement budget, reimbursement amounts and changes in the list of reimbursed medicines. Database design also allows reimbursement forecasts to be made.

The fifth year of the new Reimbursement Act has passed. The first breakthrough was at two years of the validity of the Act, when first issued reimbursement decisions has expired. At present, the situation on the market for reimbursed medicines can be considered stable. The long period of validity of the new Reimbursement Act allows to summarize changes in the reimbursed drugs market in Poland, that could be observed since the implementation of the discussed legal regulations. Experience in the analysis of reimbursement data has enabled us to carry out a reliable assessment of the evolution of the reimbursement sector. This study comprises a detailed analysis of 2016 data, starting from the reimbursement budget in the context of the total funds available to public payer for the health care system, and ending with detailed analyses on individual parts of reimbursed medicines list.

In future, the annual edition of the reimbursement report is planned, comprehensively describing developments in the reimbursed medications market in the previous calendar year. We encourage the reader to familiarize himself/herself with Compendium of reimbursement in Poland in 2016.

REIMBURSEMENT IN TOTAL

2016

1.1. NHF financial plan in 2016

For each year, the President of the Fund prepares financial plan of the National Health Fund (NHF), balanced in terms of revenues and expenses.

Figure 1 presents what part of the NHF budget (PLN 73.7 billions) was spent on reimbursement in 2016. Under the Reimbursement Act provision [1], in years 2012–2014 the total budget for reimbursement was fixed at the same level as the budget for reimbursement in 2011, only since 2015 the amount could not be less than the amount of expenditure incurred by the Fund for financing of guaranteed services in 2011, and also it could not exceed 17% of the total NHF budget (in 2016 it is about 16%).

From September 2016, due to changes in the new Reimbursement Act regarding state co-payment of medicines for seniors (project 75+), NHF budget has been endowed from state budget to finance the aid payments to medicines included in Part S of the list of reimbursed medicines for patients above 75 years old. Between 2016–2025 the maximum limit of expenditures from the state budget as a consequence of the enactment of legal changes will be PLN 8.3 billions, starting from PLN 0.13 billion in 2016 up to PLN 1.20 billion in 2025 (details in Figure 2). [3]

1.2. Reimbursement list

One of the Ministry of Health's objectives is to secure the public access to effective and safe medicinal products, while reducing treatment costs for patients. The reimbursement is an effective policy-forming instrument, shaping the state medicine policy based on the availability of products for purchase by patients (medicines, foodstuffs intended for particular nutritional uses and medical devices), whose part or the total cost is covered by NHF. The list of reimbursed medicines, foodstuffs intended for particular nutritional uses and medical devices prepares the Ministry of Health. It is divided into 4 lists:

FIGURE 1.
The total amount of the NHF budget, including reimbursement budget in 2016 [2]

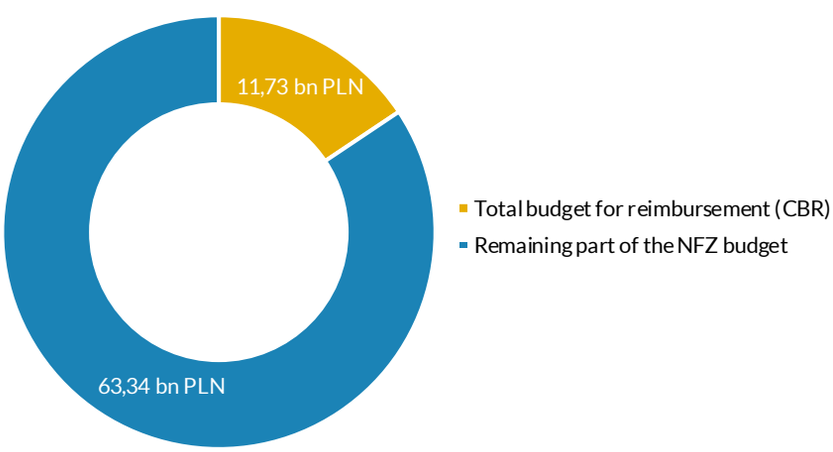
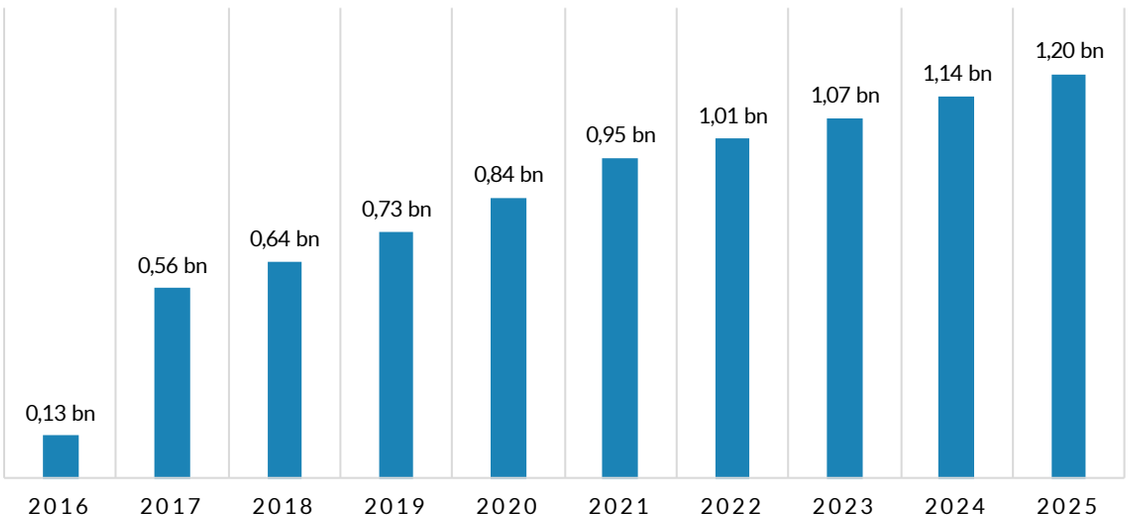


FIGURE 2.
Maximum limit of expenditures from the state budget on project 75+ between 2016–2025 [PLN] [3]



- reimbursed products issued in a pharmacy on prescription – list A,
- medicines used in drug programmess – list B,
- medicines used in chemotherapy – list C,
- reimbursed medicines issued free of charge to persons who completed 75 years of age – list S.

Bimonthly update of the reimbursement list enables efficient inclusion on it new products with proven efficacy, both original medicines and generics–medicine equivalents containing the same active substance.

1.2.1. REIMBURSEMENT AMOUNT

Total NHF expenditures on reimbursement of medicines in Poland (in pharmacies, drug programmes, chemotherapy) have increased in 2016 compared to 2015 (PLN 10.65 billion in 2015, PLN 11.18 billion in 2016). The largest portion of expenditures was intended for products from part of the list concerning reimbursed medicines issued in a pharmacy on prescription (approximately 69%). (Figure 3)

NHF expenditures incurred during consecutive months in 2016, broken down by outpatient list and treatment in hospitals is presented below (Figure 4).

1.2.2. NUMBER OF LIMIT GROUPS

Products from medicine reimbursement list are divided into limit groups. According to the Reimbursement Act, a medicine with the same international name or other international names but with a comparable therapeutic effect and a similar mechanism of action, and foodstuff intended for particular nutritional uses, medical device, shall be qualified to the limit group when applying the following criteria:

- have the same indications or uses for which they are refunded;
- have similar effectiveness.

FIGURE 3.
NHF expeditures on reimbursed medicines in 2016 [PLN]

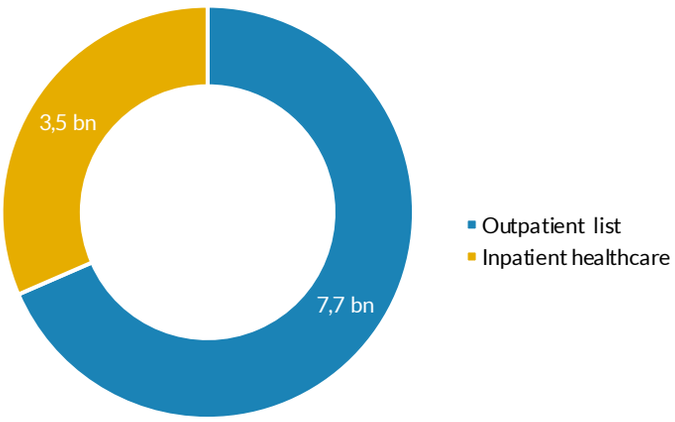
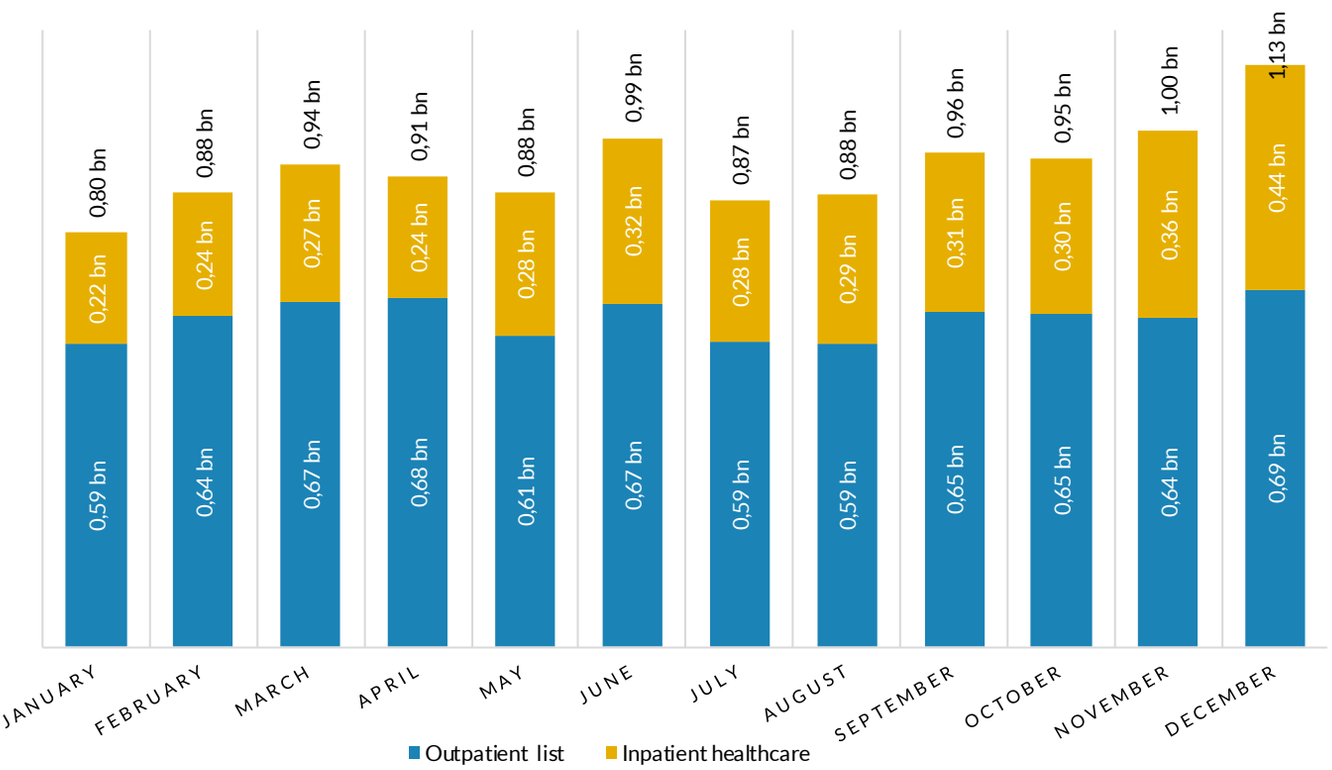


FIGURE 4.
NHF expenditures incurred on reimbursed medicines during consecutive months in 2016 [PLN]



Expenses on reimbursement of reimbursed medicines in drug programmes and chemotherapy are reported together, thus the values for drug programmes and chemotherapy are presented jointly as inpatient healthcare.

The following graphs show the number of all limit groups (Figure 5) and the number of newly created limit groups in 2016 on consecutive lists (Figure 6). In January the list contained 519 limit groups, and in November already 535 groups.

At the end of 2016, that is according to Minister of Health announcement effective since 1st November 2016, the largest number of limit groups, as many as 347, was on the outpatient, in the drug programmes part there were 107 limit groups and in the chemotherapy part there were 81 limit groups. (Figure 5)

FIGURE 5.
Number of limit groups in 2016 on consecutive lists

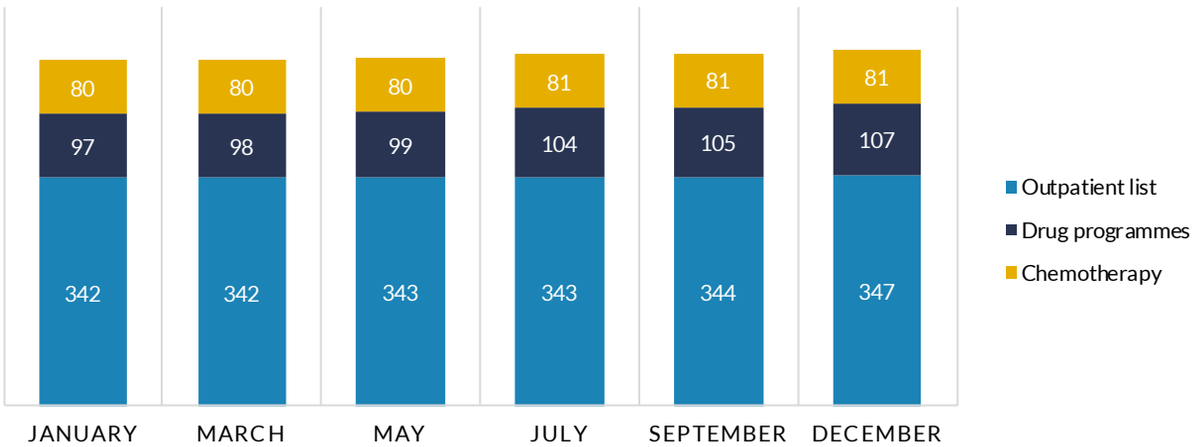
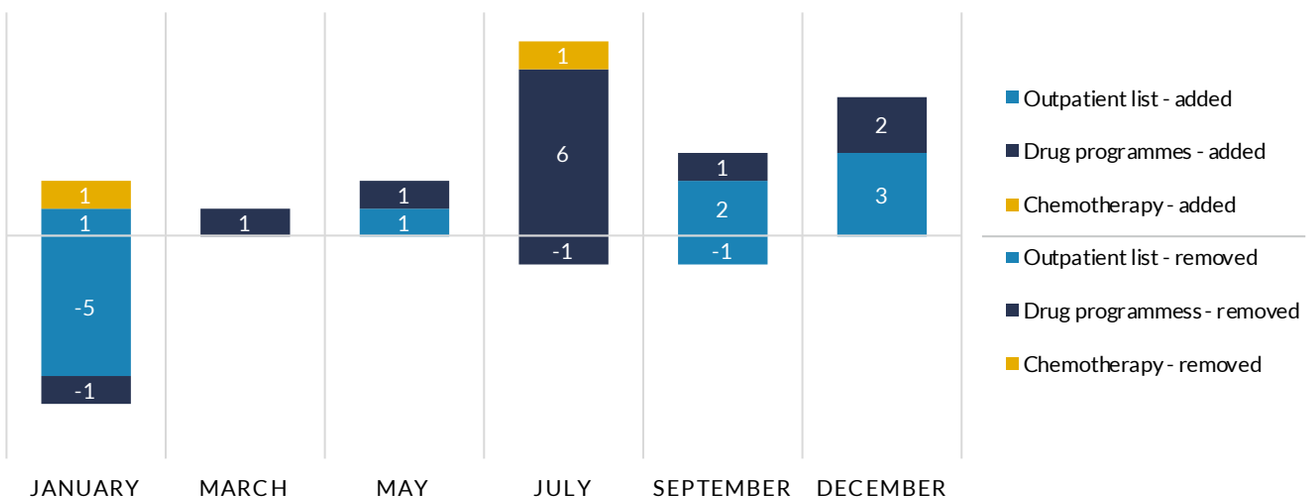


FIGURE 6.
Changes in the number of limit groups in 2016



1.2.3. NUMBER OF SUBSTANCES

Number of reimbursed substances in each part of the reimbursement list increases from one announcement to the next one. The number of substances in the outpatient list went up from 382 in January to 389 in November 2016. The strongest increase occurred in the number of substances used in drug programmes - from 93 in January to 103 in November 2016. The number of reimbursed substances for chemotherapy was between 76 in January and 77 in November 2016. (Figure 7)

In 2016 8 new substances were added to the outpatient list, to the part of the reimbursement list in drug programmes 10 substances and to the list in chemotherapy part 2 substances (details on Figure 8). At the same time, from the list have been removed 1 substance from part A and 1 substance from part B.

Details regarding medicines added to and removed from each list are presented on the following tables (Table 1 and Table 2, respectively).

FIGURE 7.
Number of all reimbursed substances in 2016 on consecutive lists

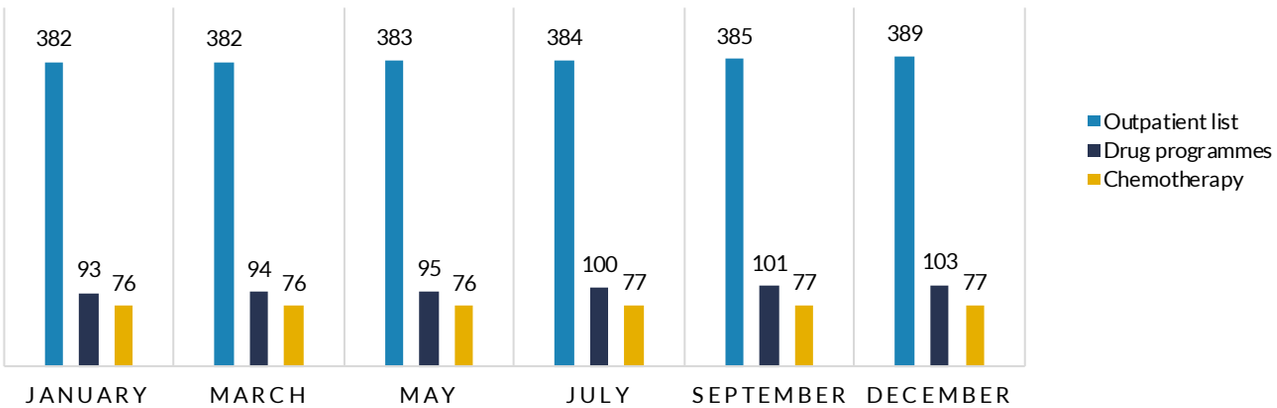


FIGURE 8.
Number of new substances added to consecutive reimbursement lists in 2016

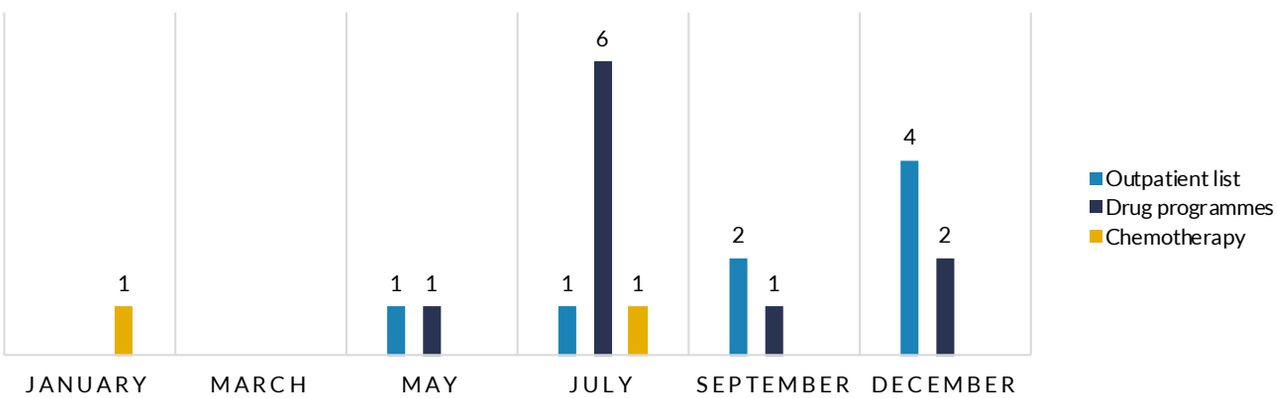


TABLE 1.
Substances added to individual lists of reimbursed medicines

DATE OF ADDITION	NUMBER OF NEW SUBSTANCES	SUBSTANCES
Outpatient list		
May	1	paricalcitol
July	1	umeclidinium bromide
September	2	pramipexole, tapentadol
November	4	agomelatine, stiripentol, febuxostat, calcipotriolum + betamethasonum
Drug programmes		
May	1	brentuximab vedotin
July	6	pembrolizumab, obinutuzumab, pertuzumab, nivolumab, peginterferon beta-1a, dimethyl fumarate
September	1	olaparib
November	2	temsirolimusum, crizotinibum
Chemotherapy		
January	1	mitoxantrone
July	1	crisantaspase

TABLE 2.

Substances removed from individual lists of reimbursed medicines

DATE OF REMOVAL	NUMBER OF REMOVED SUBSTANCES	SUBSTANCES
Outpatient list		
July	1	cromoglicic acid
Drug programmes		
May	1	interferon alfa

REIMBURSED MEDICINES ISSUED IN A PHARMACY ON PRESCRIPTION

2016

2.1. Amount of reimbursement

In accordance with NHF report for IV quarter of 2016, the planned reimbursement on the outpatient list was PLN 8.12 billion; in fact, PLN 8.07 billion were spent, which is 99.15% of the intended plan. Table 3 presents a detailed summary of the planned and realised reimbursement expenditures in individual voivodships.

The NHF expenditure on the reimbursement of medicines from the list of reimbursed drugs issued in a pharmacy on prescription amounted to PLN 7.7 billion in 2016. The largest share of the reimbursement was allocated to drugs from group *C - Cardiovascular system*, whereas the smallest share was held by drugs from group *P - Antiparasitic drugs*, insecticides and repellents. The figure below illustrates the breakdown of expenditures by specific ATC categories in 2016 (Figure 9, p. 16).

2.2. NHF and patient expenditures

Total NHF and patient expenditures on reimbursement of medicines issued in a pharmacy on prescription amounted to PLN 11.1 billion in 2016. The largest medicine categories in terms of total expenditure are *C - Cardiovascular system* and *A - Alimentary tract and metabolism*. (Figure 10, p. 17)

TABLE 3.
Plan and realization of reimbursement of medicines issued in a pharmacy on prescription in individual voivodships

VOIVODSHIP BRANCH OF THE FUND	ANNUAL FINANCIAL PLAN (IN THOUSANDS PLN)	REIMBURSEMENT (IN THOUSANDS PLN)	REALIZATION (REIMBURSEMENT / PLAN)
Dolnośląski	608 570	605 605	99.51%
Kujawsko-Pomorski	465 763	463 583	99.53%
Lubelski	445 682	443 807	99.58%
Lubuski	201 651	199 701	99.03%
Łódzki	600 920	596 915	99.33%
Małopolski	684 300	683 544	99.89%
Mazowiecki	1 098 050	1 092 964	99.54%
Opolski	199 905	196 755	98.42%
Podkarpacki	380 263	378 767	99.61%
Podlaski	218 900	216 811	99.05%
Pomorski	510 800	503 851	98.64%
Śląski	1 024 504	1 017 561	99.32%
Świętokrzyski	266 050	263 020	98.86%
Warmińsko-Mazurski	284 929	283 472	99.49%
Wielkopolski	766 574	758 065	98.89%
Zachodniopomorski	363 724	360 646	99.15%
Total	**8 120 585**	**8 065 068**	**99.32%**

Financial plan as of the 31st December 2016

Based on preparations ATC codes a percentage of patient payment was estimated, depending on the therapeutic category. The smallest share of patient surcharges in the price of the drug is found for preparations from group *L – Antineoplastic and immunomodulating agents*, whereas the greatest in case of preparations from group *C – Cardiovascular system* (detailed data in Table 4).

NHF and patient expenditures on medicines with ATC code classifying to category A - Alimentary tract and metabolism (Figure 11) amounted to PLN 1 686 million in 2016 (including NHF expenditure PLN 1 114 million). In 2016 NHF expenditures amounted to approximately 66% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *14.1 Pancreatic hormones – human insulins and analogues* (expenditures amounted to PLN 702 million).

Expenditures on medicines with ATC code classifying to category *B - Blood and blood forming organs* (Figure 12) amounted to PLN 614 million in 2016 (including NHF expenditures PLN 507 million). In 2016 NHF expenditures amounted to approximately 83% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *22.0 Low molecular weight heparins and other drugs with low molecular weight heparin activity* (expenditures amounted to PLN 547 millions).

In medicines category *C - Cardiovascular system* (Figure 13) expenditures on medicines in 2016 amounted to PLN 2 511 million (including NHF reimbursement expenditure PLN 1 207 million). In 2016 NHF expenditures amounted to approximately 48% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group

TABLE 4.
The share of patient surcharges in medicine price in 2016

ATC CATEGORY	2016
A - Alimentary tract and metabolism	33.9%
B - Blood and blood forming organs	17.5%
C - Cardiovascular system	51.9%
D - Dermatologicals	43.6%
G - Genito-urinary system and sex hormones	21.9%
H - Systemic hormonal preparations, excluding sex hormones and insulins	33.6%
J - Antiinfectives for systemic use	49.5%
L - Antineoplastic and immunomodulating agents	4.1%
M - Musculo-skeletal system	46.8%
N - Nervous system	18.4%
P - Antiparasitic products, insecticides and repellents	33.2%
R - Respiratory system	18.9%
S - Sensory organs	22.2%
V - Various	22.5%

FIGURE 11.
A - Alimentary tract and metabolism, NHF and patient expenditures [PLN]

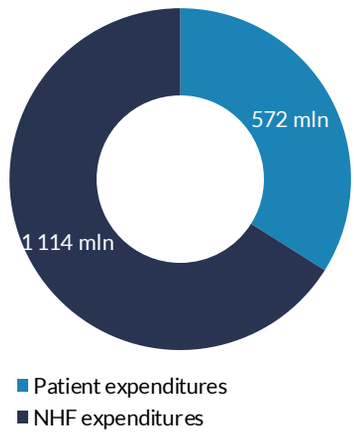


FIGURE 12.
B - Blood and blood forming organs, NHF and patient expenditures [PLN]

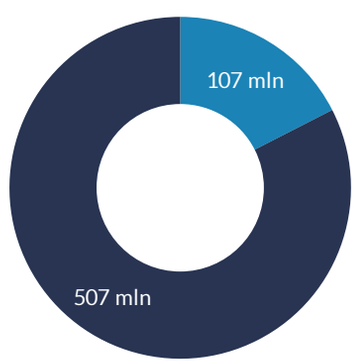


FIGURE 13.
C - Cardiovascular system, NHF and patient expenditures [PLN]

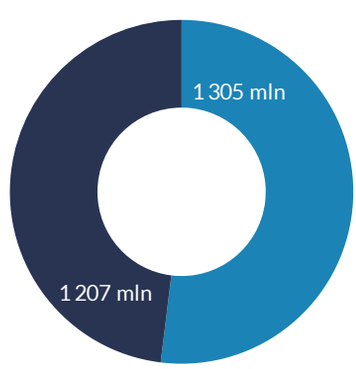


FIGURE 9.
NHF expenditures on products in individual ATC categories in 2016, Outpatient list

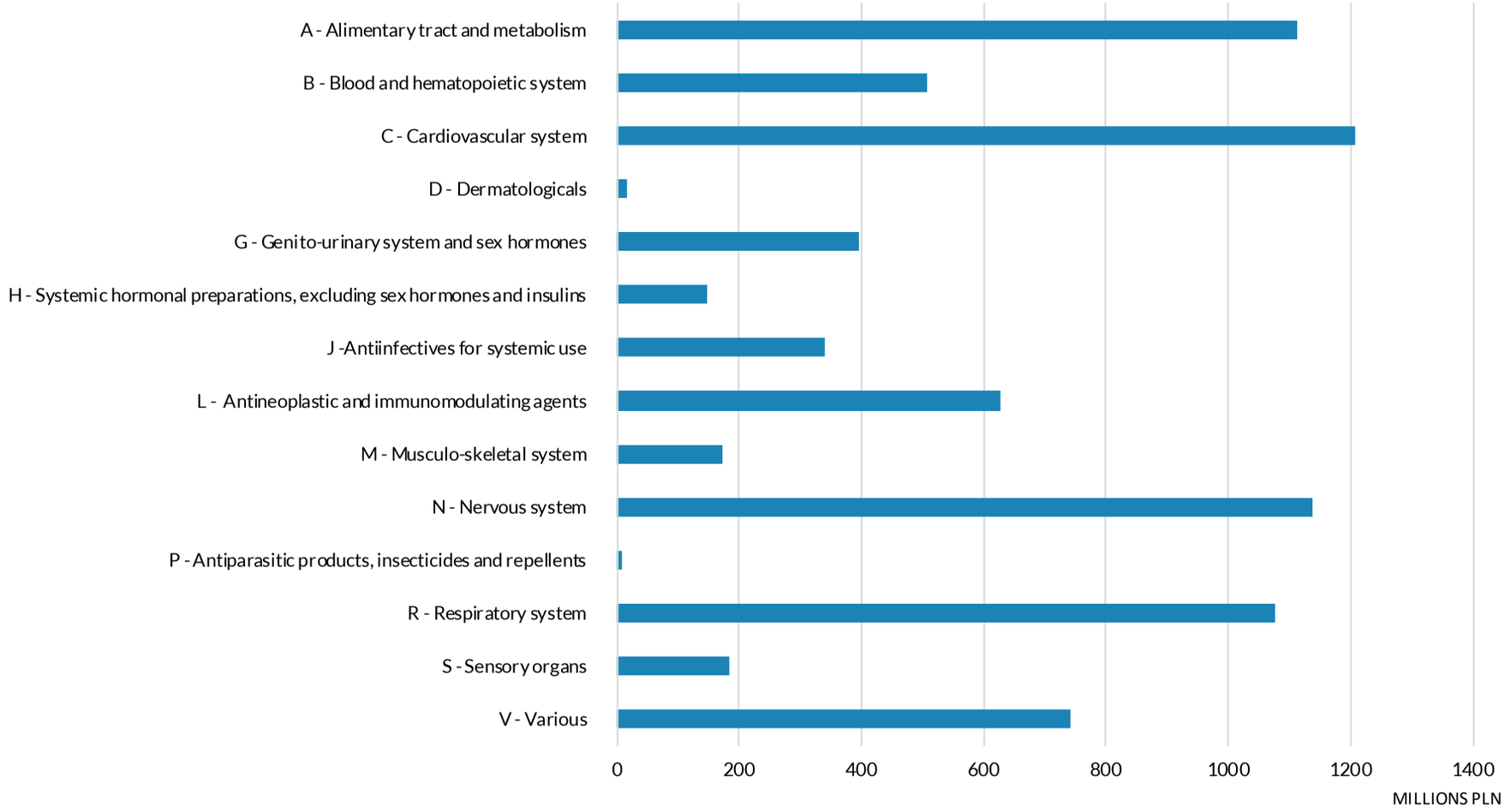
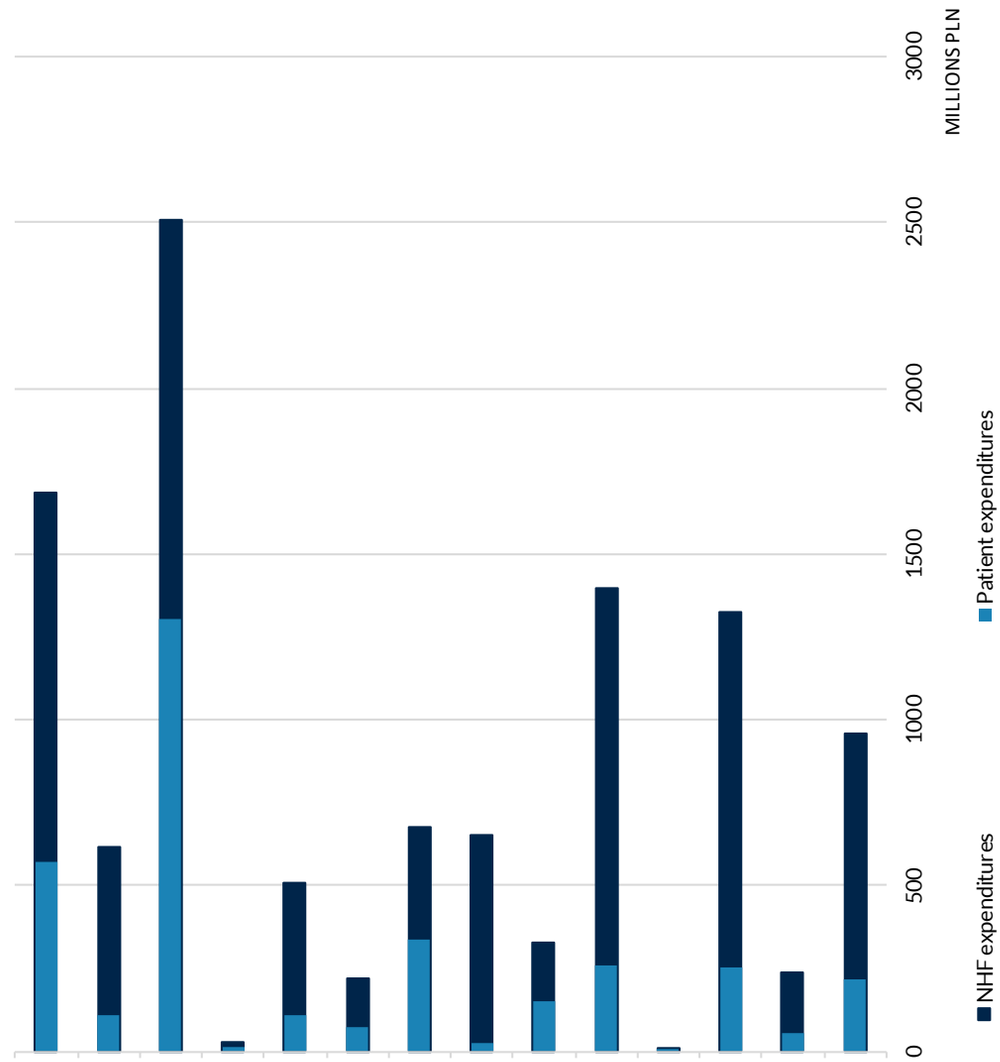


FIGURE 10.
NHF and patient expenditures on products in individual ATC categories in 2016, Outpatient list



44.0 Angiotensin converting enzyme inhibitors - single-agent preparations and combined preparations (expenditures amounted to PLN 601 million).

Expenditures on medicines with ATC code classifying to category *D - Dermatologicals* (Figure 14) amounted to PLN 30 million in 2016 (including NHF expenditures PLN 17 million). In 2016 NHF expenditures amounted to approximately 56% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *56.0 Corticosteroids for topical administration - high potency* (expenditures amounted to PLN 12 million).

Expenditures on medicines with ATC code classifying to category *G - Genito-urinary system and sex hormones* (Figure 15) amounted to PLN 506 million in 2016 (including NHF expenditures PLN 395 million). In 2016 NHF expenditures amounted to approximately 78% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *76.0 Drugs used in benign prostatic hypertrophy - alpha-adrenoreceptor antagonists* (expenditures amounted to 188 million).

Expenditures on medicines with ATC code classifying to category *H - Systemic hormonal preparations, excluding sex hormones and insulins* (Figure 16) amounted to PLN 222 million in 2016 (including NHF expenditures PLN 148 million). In 2016 NHF expenditures amounted to approximately 66% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *83.0 Thyroid hormones - levothyroxine for oral administration* (expenditures amounted to PLN 76 million).

NHF and patient expenditures on medicines with ATC code classifying to category J - *Antiinfectives for systemic use* (Figure 17) amounted to PLN 674 million in 2016 (including NHF expenditures PLN 340 million). In 2016 NHF expenditures amounted to approximately 50% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was group *90.2 Cephalosporins for parenteral administration* (expenditures amounted to PLN 111 million).

Expenditures on medicines with ATC code classifying to category *L - Antineoplastic and immunomodulating agents* (Figure 18) amounted to PLN 653 million in 2016 (including NHF expenditures PLN 626 million). In 2016 NHF expenditures amounted to approximately 96% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *133.0 Antineoplastic and immunomodulating agents - immunostimulants - granulocyte colony-stimulating factors* (expenditures amounted to PLN 163 million).

Expenditures on medicines with ATC code classifying to category *M - Musculo-skeletal system* (Figure 19) amounted to PLN 326 million in 2016 (including NHF expenditures PLN 174 million). In 2016 NHF expenditures amounted to approximately 53% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *141.1 Non-steroidal anti-inflammatory drugs for oral administration - single-agent preparations and*

FIGURE 14.
D - Dermatologicals, NHF and patient expenditures [PLN]

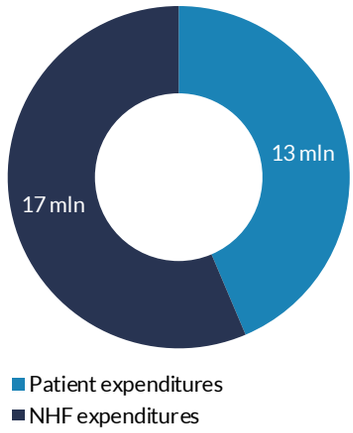


FIGURE 15.
G - Genito-urinary system and sex hormones, NHF and patient expenditures [PLN]

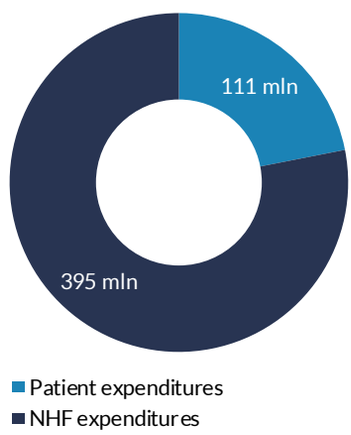


FIGURE 16.
H - Systemic hormonal preparations, excluding sex hormones and insulins, NHF and patient expenditures [PLN]

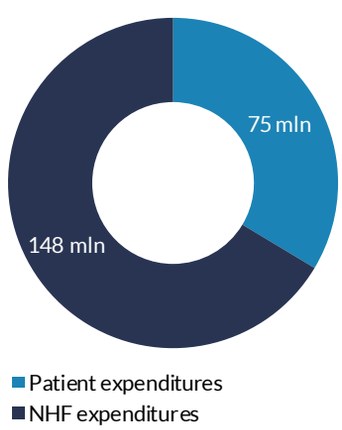


FIGURE 17.
J -Antiinfectives for systemic use, NHF and patient expenditures [PLN]

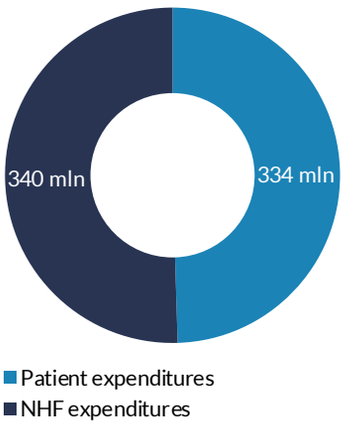


FIGURE 18.
L - Antineoplastic and immunomodulating agents, NHF and patient expenditures [PLN]

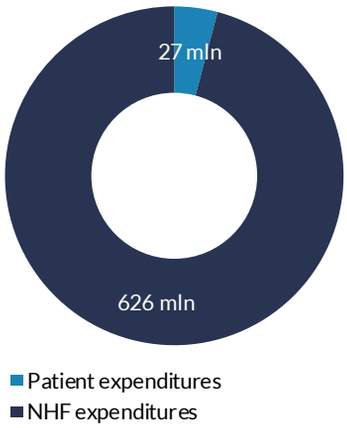


FIGURE 19.
M - Musculo-skeletal system, NHF and patient expenditures [PLN]

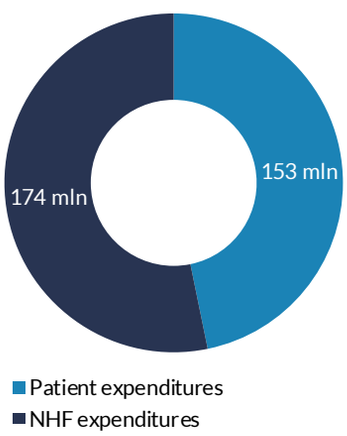


FIGURE 20.
N -Nervous system, NHF and patient expenditures [PLN]

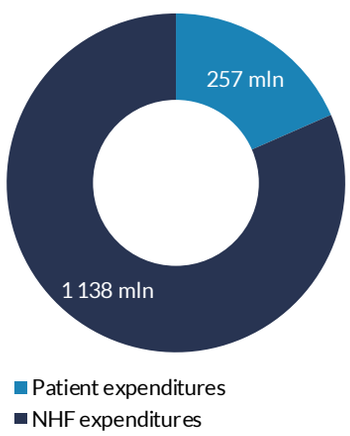


FIGURE 21.
P - Antiparasitic products, insecticides and repellents, NHF and patient expenditures [PLN]

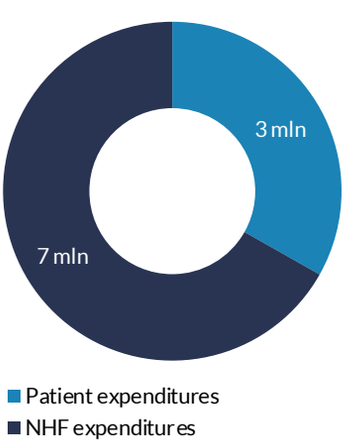
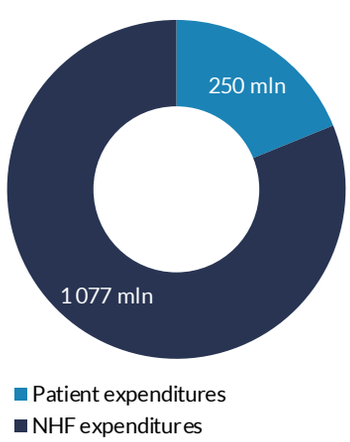


FIGURE 22.
R - Respiratory system, NHF and patient expenditures [PLN]



combinations with proton pump inhibitors - solid formulations (expenditures amounted to PLN 169 million).

Expenditures on medicines with ATC code classifying to category *N - Nervous system* (Figure 20) amounted to PLN 1 395 million in 2016 (including NHF expenditures PLN 1 138 million). In 2016 NHF expenditures amounted to approximately 82% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *178.2 Antipsychotics - olanzapine for oral administration - solid formulations* (expenditures amounted to PLN 143 million).

Expenditures on medicines with ATC code classifying to category *P - Antiparasitic products, insecticides and repellents* (Figure 21) amounted to PLN 10 million in 2016 (including NHF expenditures PLN 7 million). In 2016 NHF expenditures amounted to approximately 67% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *194.1 Anthelmintics - mebendazole* (expenditures amounted to PLN 4 million).

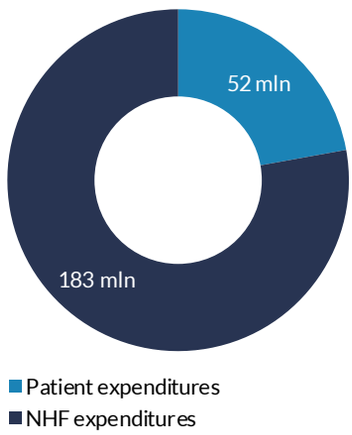
Expenditures on medicines with ATC code classifying to category *R - Respiratory system* (Figure 22) amounted to PLN 1 327 million in 2016 (including NHF expenditures PLN 1 077 million). In 2016 NHF expenditures amounted to approximately 81% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *198.0 Inhaled long-acting beta-2-adrenergic agonists - single-agent preparations* (expenditures amounted to PLN 218 million).

Expenditures on medicines with ATC code classifying to category *S - Sensory organs*

(Figure 23) amounted to PLN 235 million in 2016 (including NHF expenditures PLN 183 million). In 2016 NHF expenditures amounted to approximately 78% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *214.0 Antiglaucoma drugs - prostaglandin analogues administered in the eye - single-agent preparations and combined preparations* (expenditures amounted to PLN 126 million).

Expenditures on medicines with ATC code classifying to category *V - Various* (Figure 24) amounted to PLN 958 million in 2016 (including NHF expenditures PLN 743 million). In 2016 NHF expenditures amounted to approximately 78% of total expenditures on medicines from this group. The largest limit group in terms of total NHF and patient expenditures in 2016 was (steadily since 2012) group *219.2 Blood glucose test strips* (expenditures amounted to PLN 581 million).

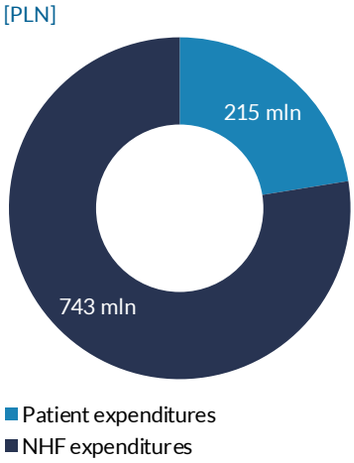
FIGURE 23.
S - Sensory organs, NHF and patient expenditures [PLN]



2.3. New substances

In 2016 the list of reimbursed medicines issued in a pharmacy on prescription was extended to incorporate 8 additional active ingredients (including previously not reimbursed combinations of substances), from which 4 embraced in November (Figure 25). In 2016 most, as many as 4 new active substances have been covered by the reimbursement within limit groups comprising medicines acting on the nervous system: *170.0 Antiparkinson drugs - dopamine receptor agonists*, *153.5 Opioid analgesics - tapentadol*, *225.1 Antidepressants - agomelatine*, *244.1 Antiepileptic drugs for oral administration - stiripentol* (Table 5).

FIGURE 24.
V - Various, NHF and patient expenditures [PLN]



2.4. New limit groups

In 2016 on the list of reimbursed medicines issued in a pharmacy on prescription have appeared a total of 7 new limit groups (Figure 26, Table 6).

TABLE 5.
New active substances covered by the reimbursement in 2016 within reimbursed medicines issued in a pharmacy on prescription

DATE OF ENTRY	ACTIVE SUBSTANCE	LIMIT GROUP	ATC CATEGORY
May	**paricalcitol**	86.1 Drugs affecting calcium metabolism - other anti-parathyroid agents	H - Systemic hormonal preparations, excluding sex hormones and insulins
July	**umeclidinium bromide**	201.2 Inhaled long-acting anticholinergic drugs - single-agent preparations	R - Respiratory system
September	**pramipexole**	170.0 Antiparkinson drugs - dopamine receptor agonists	N - Nervous system
September	**tapentadol**	153.5 Opioid analgesics - tapentadol	N - Nervous system
November	**agomelatine**	225.1 Antidepressants - agomelatine	N - Nervous system
November	**stiripentol**	244.1 Antiepileptic drugs for oral administration - stiripentol	N - Nervous system
November	**febuxostat**	145.0 Antigout drugs – allopurinol	M - Musculo-skeletal system
November	**calcipotriolum + betamethasonum**	18.3 Vitamin D and analogues - calcipotriol combined with corticosteroids for topical administration	D - Dermatologicals

FIGURE 25.
Number of new active substances on subsequent announcements in 2016

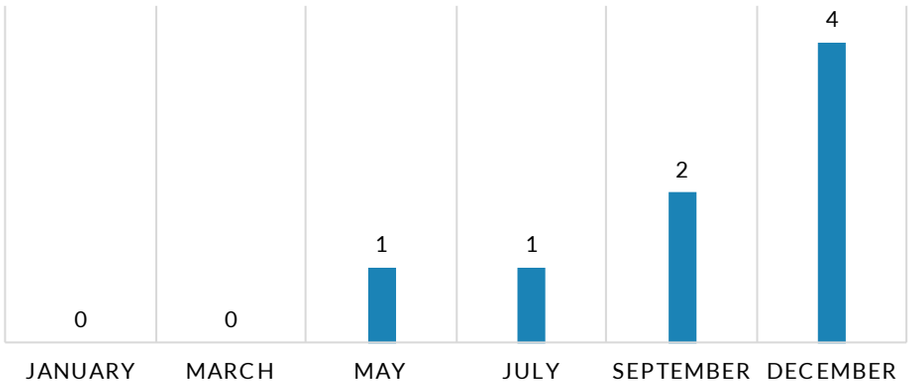


FIGURE 26.
Number of newly created limit groups in 2016, Outpatient list

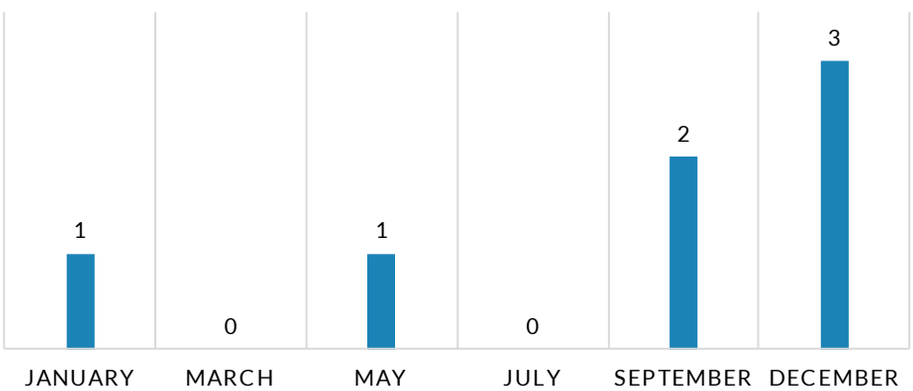


TABLE 6.
New limit groups in 2016, Outpatient list

DATE OF ENTRY	LIMIT GROUP	ATC CATEGORY
January	11.1 Oral corticosteroids for topical gastrointestinal - budesonide - ulcerative colitis	A - Alimentary tract and metabolism
May	86.1 Drugs affecting calcium metabolism - other anti-parathyroid agents	H - Systemic hormonal preparations, excluding sex hormones and insulins
September	153.5 Opioid analgesics - tapentadol	N - Nervous system
September	178.12 Antipsychotics - aripiprazole for parenteral administration - extended release formulations	N - Nervous system
November	244.1 Antiepileptic drugs for oral administration - stiripentol	N - Nervous system
November	18.3 Vitamin D and analogues - calcipotriol combined with corticosteroids for topical administration	D - Dermatologicals
November	225.1 Antidepressants - agomelatine	N - Nervous system

REIMBURSED MEDICINES USED IN DRUG PROGRAMMES

2016

A treatment under the program is carried out using innovative, expensive active substances, which are not financed by other guaranteed services. It is carried out for selected disease entities and covers patient groups meeting strict criteria (inclusion/exclusion). From mid-2012 a total of 80 drug programmes have been created, from which 28 concerned oncological indications, and 52 non-oncological indications.

3.1. Amount of reimbursement

In accordance with NHF report for IV quarter of 2016, the planned reimbursement on the drug programmes was PLN 2.93 billion, concluded contracts amounted to PLN 2.88 billion, in fact, PLN 2.85 billion were spend, which is 97.21% of the intended plan. Table 7 presents a detailed summary for the planned and realised reimbursement expenditures in individual voivodships.

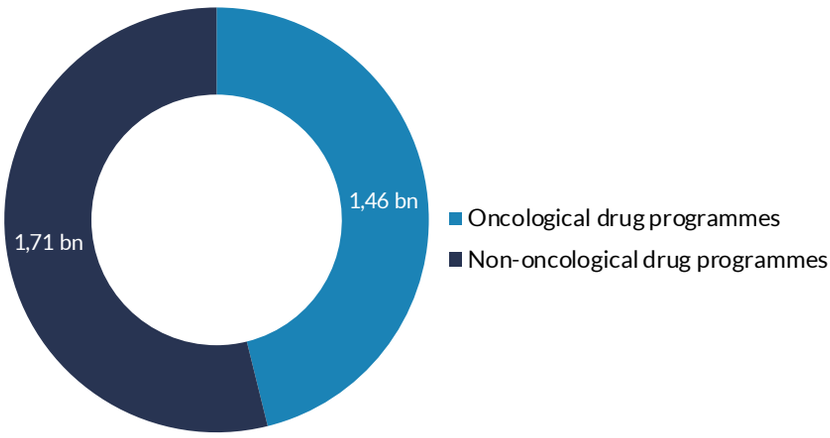
Total NHF expenditure on the reimbursement of medicines used within drug programmes amounted to PLN 3.17 billion (this amount includes also reimbursement within chemotherapy in cases where the medicine is reimbursed in both drug and chemotherapy programmes). Figure 27 presents amount of NHF reimbursement on medicines used within oncological and non-oncological drug programmes in 2016.

TABLE 7.
Plan and realization of reimbursement of medicines issued in drug programmes in individual voivodships

VOIVODSHIP BRANCH OF THE FUND	ANNUAL FINANCIAL PLAN (IN THOUSANDS PLN)	CONTRACTED FOR A GIVEN YEAR (IN THOUSANDS PLN)	REALIZED (IN THOUSANDS PLN)	PLAN REALIZATION
Dolnośląski	232 754	237 292	220 010	94.52%
Kujawsko-Pomorski	147 512	152 582	146 581	99.37%
Lubelski	151 436	137 943	151 426	99.99%
Lubuski	67 171	53 886	65 722	97.84%
Łódzki	198 571	183 900	196 257	98.83%
Małopolski	283 169	289 295	274 945	97.10%
Mazowiecki	487 423	553 200	477 155	97.89%
Opolski	67 835	48 827	62 667	92.38%
Podkarpacki	158 813	138 261	152 743	96.18%
Podlaski	75 050	68 092	69 874	93.10%
Pomorski	166 000	149 054	161 639	97.37%
Śląski	355 150	366 432	348 990	98.27%
Świętokrzyski	98 916	84 974	93 273	94.30%
Warmińsko-Mazurski	89 777	75 176	87 855	97.86%
Wielkopolski	247 420	235 977	236 067	95.41%
Zachodniopomorski	107 066	105 900	107 066	100.00%
Total	**2 934 063**	**2 880 789**	**2 852 270**	**97,21%**

Financial plan as of the 31st December 2016

FIGURE 27.
Amount of reimbursement on medicines within drug programmes in 2016, broken down by oncological and non-oncological programmes [PLN]



Amount of reimbursement on medicines reimbursed in drug and chemotherapy programmes is reported jointly, thus the data comprise the amount paid for the medicines within list C, according to indications from both lists.

For each calendar year from 2012 onwards, the limit group with the highest reimbursement amount was group 1082.0 Trastuzumab, in which is reimbursed Herceptin, used in drug programmes *B.9. Treatment of breast cancer* and *B.58. Treatment of advanced gastric cancer*. It should be borne in mind, that the data re ported by the NHF include information on sales of medicines jointly within drug and chemotherapy programmes. The following table presents 10 limit groups of medicines reimbursed within drug programmes with the highest reimbursement amount in 2016 (Table 8).

3.2. New substances

In 2016 the list of reimbursed medicines used in drug programmes was extended to incorporate 10 active substances (details on Figure 28, Table 9). The greatest change was observed in July, when to the list of drugs used in drug programmes was added 6 new substances.

TABLE 8.
Limit groups with the highest reimbursement amount in 2016, drug programmes

NO	GROUP CODE	GROUP NAME	AMOUNT OF REIMBURSEMENT [PLN]
1	1082.0	Trastuzumab	300.76 million
2	1035.0	Rituximab	225.30 million
3	1135.0	Ntivirals - ombitasvir, paritaprevir, ritonavir	212.63 million
4	1135.3	Antivirals - ledipasvir, sofosbuvir	153.56 million
5	1120.0	Lenalidomide	122.44 million
6	1050.1	TNF inhibitors - adalimumab	110.67 million
7	1024.5	Interferon beta-1b	87.29 million
8	1064.0	Imatinib	80.21 million
9	1095.0	Antineoplastic agents, monoclonal antibodies - bevacizumab	79.75 million
10	1050.2	TNF inhibitors - etanercept	75.44 million

FIGURE 28.
Number of substances included in the reimbursement in 2016, Drug programmes

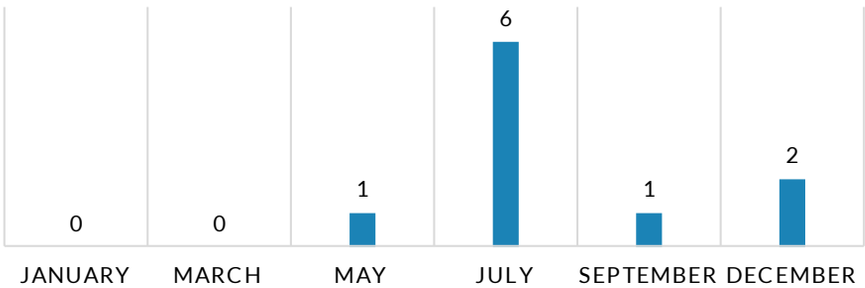


TABLE 9.
New active substances covered by reimbursement within the list of reimbursed medicines used in drug programmes

DATE OF ENTRY	NUMBER OF NEW SUBSTANCES	SUBSTANCES	CODE AND NAME OF DRUG PROGRAMMES
May	1	brentuximab vedotin	B.77. Treatment of refractory and relapsing forms of lymphoma CD30 +
July	6	obinutuzumab	B.79. Treatment of chronic lymphocytic leukemia with obinutuzumab
		pembrolizumab	B.59. Treatment of melanoma of the skin or mucous membranes
		nivolumab	B.59. Leczenie czerniaka skóry lub błon śluzowych
		pertuzumab	B.9. Treatment of breast cancer
		peginterferon beta-1a	B.29. Treatment of multiple sclerosis
		dimethyl fumarate	B.29. Treatment of multiple sclerosis
September	1	olaparib	B.80. Maintenance treatment of patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer with olaparib
November	2	temsirolimusum	B.10. Treatment of kidney cancer
		crizotinibum	B.6. Treatment of non-small-cell lung cancer

3.3. Number of Drug programmes

Drug programmes are functioning since July 2012. Since over 4 years, their number has significantly increased. The number of oncological drug programmes has doubled since 2012, with 12 new oncological programmes being created. The number of non-oncological drug programmes has increased since 2012 from 30 to 49. The number of drug programmes on following lists of 2016 is presented below, broken down by oncological and non-oncological programmes (Figure 29) and the number of new drug programmes in 2016 (Figure 30).

TABLE 10.
Drug programmes created in 2016

DATE OF ENTRY	DRUG PROGRAMMES
May	B.77. Treatment of refractory and relapsing forms of lymphoma CD30 +
July	B.78. Treatment of symptomatology of primary immunodeficiencies (PIDs) in adult patients with the use human normal immunoglobulin administered with recombinant human hyaluronidase
July	B.79. Treatment of chronic lymphocytic leukemia with obinutuzumab
September	B.80. Maintenance treatment of patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer with olaparib

FIGURE 29.
Number of drug programmeson succeeding lists of 2016, broken down by oncological and non-oncological programmes

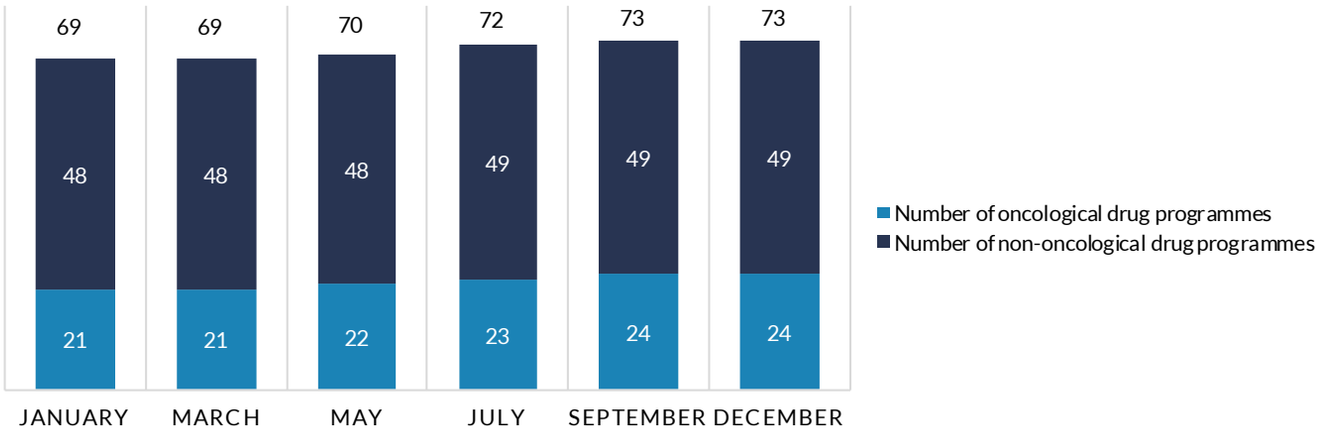
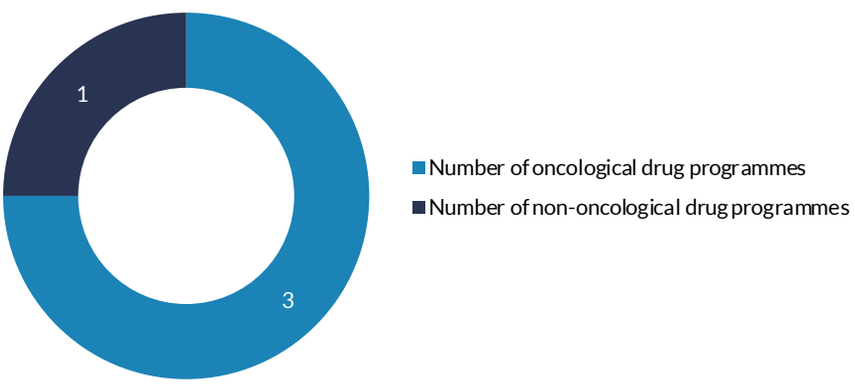


FIGURE 30.
Number of new drug programmes in 2016, broken down by oncological and non-oncological programmes



3.4. Number of patients

In 2016 within drug programmes 90 505 persons were treated. The number of patients in drug programmes was assumed to be equal to the number of persons charged for diagnostic procedures. Only in case of programmes B.39., B.40., B.57. and B.69. it was assumed, that the number of patients equals the number of persons, for whom substances have been accounted for (as there is no specific diagnostics in these programmes). Figure 31 presents the number of persons treated, broken down by oncological and non-oncological programmes.

The following table (Table 11) presents compiled number of persons reported in each drug programmes in 2016. Most, namely more than 11 thousand patients were treated within drug programmes *B.70. Treatment neovascular (wet) macular degeneration forms related to age*. The second largest population received treatment within the program *B.29. Treatment of multiple sclerosis*, within which almost 9 thousand patients were treated in 2016.

FIGURE 31.
Number of persons treated within drug programmes in 2016

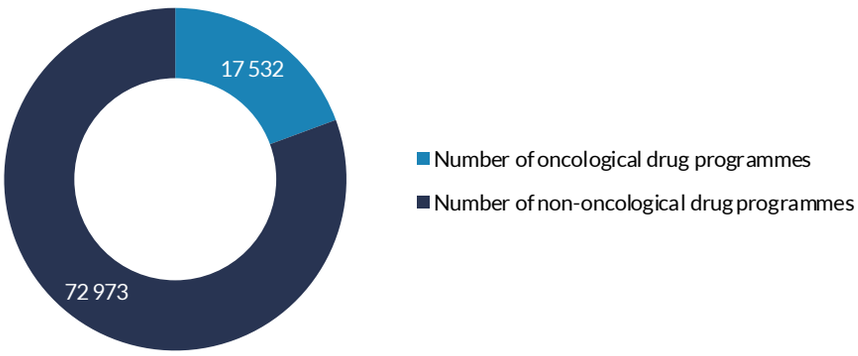


TABLE 11.
Number of patients treated within drug programmes in 2016, broken down by oncological and non-oncological programmes

ANNEX REF. NO	DRUG PROGRAMMES	NUMBER OF PATIENTS	ONCOLOGICAL
B.1.	TREATMENT OF CHRONIC HEPATITIS B	6915	No
B.2.	TREATMENT OF CHRONIC HEPATITIS C	1792	No
B.3.	TREATMENT OF GASTROINTESTINAL STROMAL TUMORS (GIST)	652	Yes
B.4.	TREATMENT OF ADVANCED COLON CANCER	1941	Yes
B.5.	TREATMENT OF HEPATOCELLULAR CARCINOMA	263	Yes
B.6.	TREATMENT OF NON-SMALL-CELL LUNG CANCER	1103	Yes
B.8.	TREATMENT OF SOFT TISSUE SARCOMAS	149	Yes
B.9.	TREATMENT OF BREAST CANCER	5051	Yes
B.10.	TREATMENT OF KIDNEY CANCER	1928	Yes
B.12.	TREATMENT OF MALIGNANT LYMPHOMAS	1688	Yes
B.14.	TREATMENT OF CHRONIC MYELOID LEUKEMIA	915	Yes
B.15.	PREVENTION OF BLEEDING IN CHILDREN WITH HEMOPHILIA A AND B	329	No
B.17.	TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN CHILDREN	324	No
B.18.	TREATMENT OF PRECOCIOUS PUBERTY	581	No
B.19.	TREATMENT OF SHORT STATURE CHILDREN WITH ISOLATED GROWTH HORMONE DEFICIENCY	4204	No
B.20.	TREATMENT OF SHORT STATURE CHILDREN WITH SEVERE PRIMARY IGF-1 DEFICIENCY	35	No
B.21.	TREATMENT OF SEVERE CONGENITAL HYPERHOMOCYSTEINEMIA	16	No
B.22.	TREATMENT OF POMPE DISEASE	31	No
B.23.	TREATMENT OF GAUCHER'S DISEASE	63	No
B.24.	TREATMENT OF HURLER DISEASE	11	No
B.25.	TREATMENT OF MUCOPOLYSACCHARIDOSIS TYPE II (HUNTER SYNDROME)	17	No
B.26.	TREATMENT OF MUCOPOLYSACCHARIDOSIS TYPE VI (MAROTEAUX – LAMY SYNDROME)	2	No
B.27.	TREATMENT OF CHRONIC LUNG INFECTIONS IN PATIENTS WITH CYSTIC FIBROSIS	85	No
B.28.	TREATMENT OF FOCAL DYSTONIA AND HEMIFACIAL SPASM	3561	No
B.29.	TREATMENT OF MULTIPLE SCLEROSIS	8854	No

ANNEX REF. NO	DRUG PROGRAMMES	NUMBER OF PATIENTS	ONCOLOGICAL
B.30.	TREATMENT OF SPASTICITY IN CEREBRAL PALSY	1500	No
B.31.	TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH)	463	No
B.32.	TREATMENT OF CROHN'S DISEASE	1061	No
B.33.	TREATMENT OF RHEUMATOID ARTHRITIS AND AGGRESSIVE JUVENILE IDIOPATHIC ARTHRITIS	4151	No
B.35.	TREATMENT OF AGGRESSIVE PSORIATIC ARTHRITIS	1076	No
B.36.	TREATMENT OF PATIENTS WITH SEVERE ACTIVE FORM OF ANKYLOSING SPONDYLITIS WITH TNF ALFA INHIBITORS	2126	No
B.37.	TREATMENT OF ANEMIA IN CHRONIC RENAL FAILURE	1407	No
B.38.	TREATMENT OF SHORT STATURE CHILDREN WITH CHRONIC RENAL FAILURE	49	No
B.39.	TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN HEMODIALYZED PATIENTS	3115	No
B.40.	PROPHYLAXIS OF RS VIRUS INFECTIONS	2232	No
B.41.	TREATMENT OF CHILDREN WITH PRADER-WILLI SYNDROME	154	No
B.42.	TREATMENT OF SHORT STATURE CHILDREN WITH TURNER SYNDROME	438	No
B.43.	TREATMENT OF HEPATITIS B IN TRANSPLANT RECIPIENTS OR PATIENTS WITH LYMPHOMAS, TREATED WITH RITUXIMAB	496	No
B.44.	TREATMENT OF SEVERE ALLERGIC IGE-DEPENDENT ASTHMA WITH OMALIZUMAB	368	No
B.46.	TREATMENT OF MULTIPLE SCLEROSIS AFTER FAILURE OF FIRST LINE THERAPY OR RAPIDLY PROGRESSING MULTIPLE SCLEROSIS	803	No
B.48.	TREATMENT OF CUTANEOUS MELANOMA	251	Yes
B.49.	ORAL TREATMENT OF IRON OVERLOAD	104	No
B.50.	TREATMENT OF PATIENTS WITH ADVANCED OVARIAN CANCER	635	Yes
B.52.	TREATMENT OF LOCALLY ADVANCED SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK IN COMBINATION WITH RADIOTHERAPY	34	Yes
B.53.	TREATMENT OF WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE NEOPLASM	57	Yes
B.54.	LENALIDOMIDE IN THE TREATMENT OF PATIENTS WITH REFRACTORY OR RECURRENT MULTIPLE MYELOMA	1096	Yes
B.55.	INDUCTION OF REMISSION IN ULCERATIVE COLITIS	187	No
B.56.	TREATMENT OF CASTRATION-RESISTANT PROSTATE CANCER	896	Yes
B.57.	TREATMENT OF UPPER LIMB SPASTICITY AFTER STROKE WITH BOTULINUM TOXIN TYPE A	1910	No
B.58.	TREATMENT OF ADVANCED GASTRIC CANCER	130	Yes
B.60.	TREATMENT OF TYPE I GAUCHER DISEASE	8	No
B.61.	TREATMENT OF EARLY CHILDHOOD FORMS OF NEPHROPATHIC CYSTINOSIS	4	No
B.64.	TREATMENT OF SHORT STATURED CHILDREN BORNED TOO SMALL COMPARED TO THE DURATION OF PREGNANCY WITH GROWTH HORMONE	174	No
B.65.	TREATMENT OF PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA WITH DASATINIB	43	Yes
B.62.	TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN ADULT PATIENTS	360	No
B.63.	TREATMENT OF NON-SMALL-CELL LUNG CANCER WITH AFATINIB	130	Yes
B.66.	TREATMENT OF MYCOSIS FUNGOIDES OR SÉZARY`S DISEASE WITH BEXAROTENE	61	Yes
B.69.	PARICALCITOL TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN HEMODIALYSIS PATIENTS	2135	No
B.67.	TREATMENT TRANSFUSIONS IMMUNOGLOBULIN NEUROLOGICAL DISORDER	694	No

ANNEX REF. NO	DRUG PROGRAMMES	NUMBER OF PATIENTS	ONCOLOGICAL
B.68.	TREATMENT OF PULMONARY ARTERIAL HYPERTENSION SILDENAFIL AND EPOPROSTENOL (PAH)	412	No
B.70.	TREATMENT NEOVASCULAR (WET) MACULAR DEGENERATION FORMS RELATED TO AGE	11342	No
B.71.	TREATMENT OF CHRONIC HEPATITIS C INTERFERON-FREE THERAPY	8677	No
B.72.	SKIN CANCER TREATMENT WITH DABRAFENIB	171	Yes
B.74.	TREATMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH)	110	No
B.75.	TREATMENT ACTIVE FORM GRANULOMATOSIS VASCULITIS (GPA) OR MICROSCOPIC VASCULITIS (MPA)	41	No
B.73.	TREATMENT NEUROGENIC DETRUSOR OVERACTIVITY	55	No
B.47.	TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS	480	No
B.76.	TREATMENT TYROSINEMIA TYPE 1 (HT-1)	15	No
B.77.	TREATMENT OF REFRACTORY AND RELAPSING FORMS OF LYMPHOMA CD30 +	53	Yes
B.78.	TREATMENT OF SYMPTOMATOLOGY OF PRIMARY IMMUNODEFICIENCIES (PIDS) IN ADULT PATIENTS WITH THE USE HUMAN NORMAL IMMUNOGLOBULIN ADMINISTERED WITH RECOMBINANT HUMAN HYALURONIDASE	6	No
B.79.	TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA WITH OBINUTUZUMAB	3	Yes
B.59.	TREATMENT OF MELANOMA OF THE SKIN OR MUCOUS MEMBRANES	275	Yes
B.80.	MAINTENANCE TREATMENT OF PATIENTS WITH PLATINUM-SENSITIVE RELAPSED HIGH GRADE SEROUS EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WITH OLAPARIB	7	Yes

The number of patients in drug programmes was assumed to be equal to the number of persons charged for diagnostic procedures. Only in case of programmes B.39., B.40., B.57. and B.69. it was assumed, that the number of patients equals the number of persons, for whom substances have been accounted for (as there is no specific diagnostics in these programmes).

3.5. Contracts for medicines, procedures and qualifications

The total value of agreements concluded by NHF in 2016 within the scope of drug programmes in hospital treatment is presented below (Figure 32). The figure envisages drug programmes breakdown into oncological and non-oncological, as well as on medicines, procedures and services related to qualification of patients for programmes. Discussed data are also provided in a tabular form (Table 12). In both, oncological and non-oncological programmes, the largest share of payer's expenses is accounted for by contracts on medicines (about 90%).

The following table (Table 13) presents the value of contracts for each drug programmes in 2016. The largest contract value was concluded for program *B.71. Treatment of chronic hepatitis c interferon-free therapy*; the second largest amount contracted is the oncological program *B.9. Treatment of breast cancer.*

FIGURE 32.
Value of contracts concluded by NHF in 2016

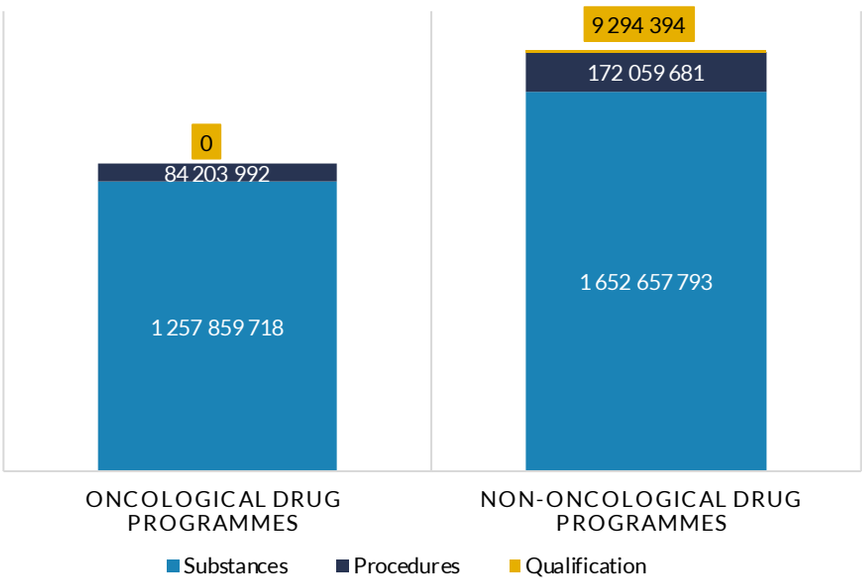


TABLE 12.
Value of agreements concluded by NHF in 2016

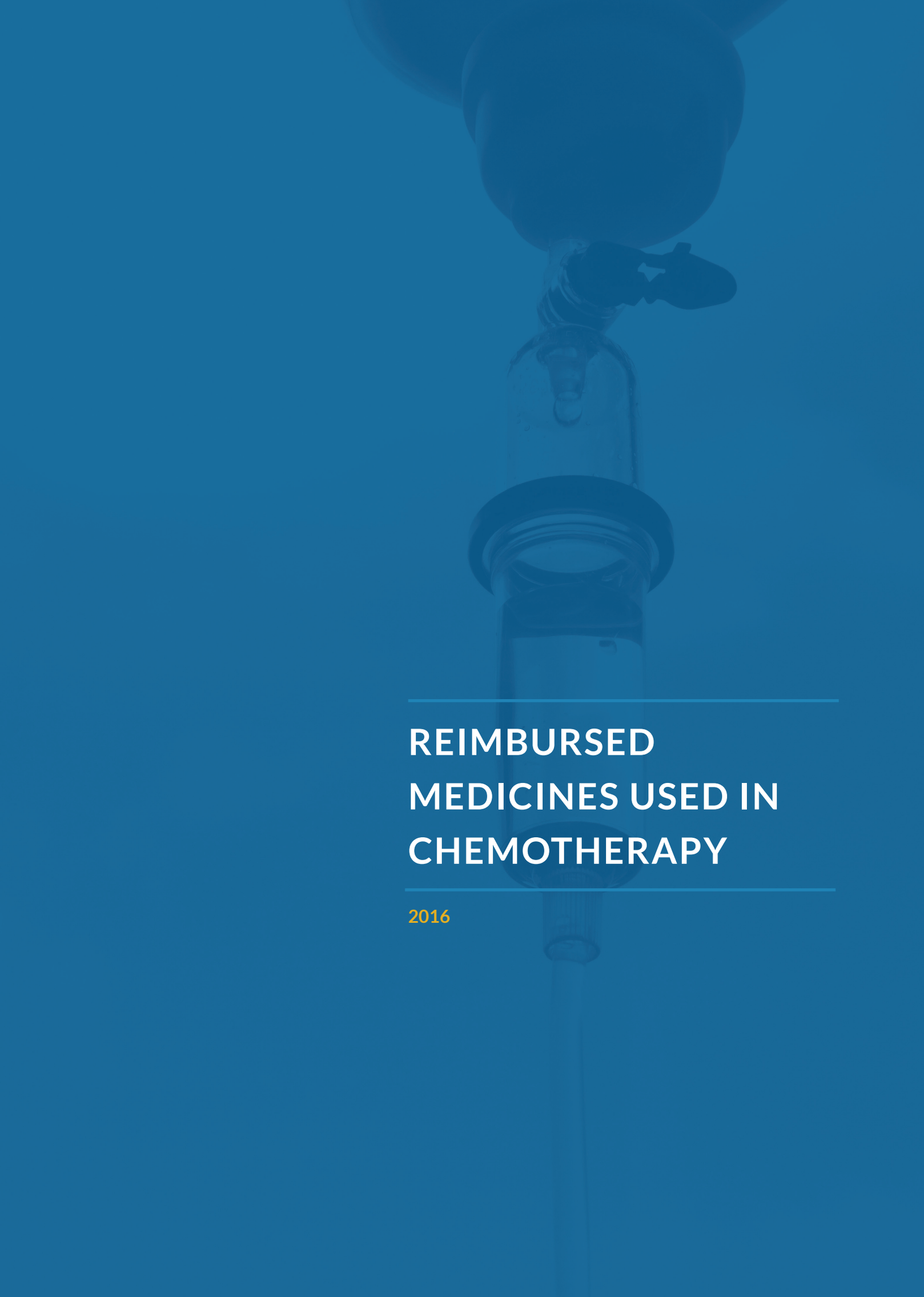
CATEGORY	VALUE OF AGREEMENTS CONCLUDED [PLN]
Substances - Oncological Drug programmes	1 257.86 million
Procedures - Oncological Drug programmes	84.20 million
Qualifications - Oncological Drug programmes	0.00 million
Total - Oncological Drug programmes	**1 342.06 million**
Substances - Non-oncological Drug programmes	16 52.66 million
Procedures - Non-oncological Drug programmes	172.06 million
Qualifications - Non-oncological Drug programmes	9.29 million
Total - Non-oncological Drug programmes	**1 834.01 million**
Total	**3 176.08 million**

TABLE 13.
Value of contracts in individual drug programmes in 2016, broken down by oncological and non-oncological programmes

ANNEX REF. NO	DRUG PROGRAMMES	CONTRACT VALUE [PLN]	ONCOLOGICAL
B.1.	TREATMENT OF CHRONIC HEPATITIS B	91.24 mln	No
B.2.	TREATMENT OF CHRONIC HEPATITIS C	24.42 mln	No
B.3.	TREATMENT OF GASTROINTESTINAL STROMAL TUMORS (GIST)	92.15 mln	Yes
B.4.	TREATMENT OF ADVANCED COLON CANCER	137.12 mln	Yes
B.5.	TREATMENT OF HEPATOCELLULAR CARCINOMA	13.37 mln	Yes
B.6.	TREATMENT OF NON-SMALL-CELL LUNG CANCER	37.88 mln	Yes
B.8.	TREATMENT OF SOFT TISSUE SARCOMAS	17.88 mln	Yes
B.9.	TREATMENT OF BREAST CANCER	349.94 mln	Yes
B.10.	TREATMENT OF KIDNEY CANCER	138.71 mln	Yes

ANNEX REF. NO	DRUG PROGRAMMES	CONTRACT VALUE [PLN]	ONCOLOGICAL
B.12.	TREATMENT OF MALIGNANT LYMPHOMAS	76.47 mln	Yes
B.14.	TREATMENT OF CHRONIC MYELOID LEUKEMIA	123.07 mln	Yes
B.15.	PREVENTION OF BLEEDING IN CHILDREN WITH HEMOPHILIA A AND B	42.51 mln	No
B.17.	TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN CHILDREN	9.28 mln	No
B.18.	TREATMENT OF PRECOCIOUS PUBERTY	3.58 mln	No
B.19.	TREATMENT OF SHORT STATURE CHILDREN WITH ISOLATED GROWTH HORMONE DEFICIENCY	28.52 mln	No
B.20.	TREATMENT OF SHORT STATURE CHILDREN WITH SEVERE PRIMARY IGF-1 DEFICIENCY	4.67 mln	No
B.21.	TREATMENT OF SEVERE CONGENITAL HYPERHOMOCYSTEINEMIA	0.43 mln	No
B.22.	TREATMENT OF POMPE DISEASE	32.39 mln	No
B.23.	TREATMENT OF GAUCHER'S DISEASE	48.79 mln	No
B.24.	TREATMENT OF HURLER DISEASE	12.09 mln	No
B.25.	TREATMENT OF MUCOPOLYSACCHARIDOSIS TYPE II (HUNTER SYNDROME)	32.07 mln	No
B.26.	TREATMENT OF MUCOPOLYSACCHARIDOSIS TYPE VI (MAROTEAUX – LAMY SYNDROME)	3.69 mln	No
B.27.	TREATMENT OF CHRONIC LUNG INFECTIONS IN PATIENTS WITH CYSTIC FIBROSIS	3.02 mln	No
B.28.	TREATMENT OF FOCAL DYSTONIA AND HEMIFACIAL SPASM	12.13 mln	No
B.29.	TREATMENT OF MULTIPLE SCLEROSIS	246.78 mln	No
B.30.	TREATMENT OF SPASTICITY IN CEREBRAL PALSY	4.54 mln	No
B.31.	TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH)	69.99 mln	No
B.32.	TREATMENT OF CROHN'S DISEASE	31.88 mln	No
B.33.	TREATMENT OF RHEUMATOID ARTHRITIS AND AGGRESSIVE JUVENILE IDIOPATHIC ARTHRITIS	135.89 mln	No
B.35.	TREATMENT OF AGGRESSIVE PSORIATIC ARTHRITIS	37.95 mln	No
B.36.	TREATMENT OF PATIENTS WITH SEVERE ACTIVE FORM OF ANKYLOSING SPONDYLITIS WITH TNF ALFA INHIBITORS	77.14 mln	No
B.37.	TREATMENT OF ANEMIA IN CHRONIC RENAL FAILURE	4.89 mln	No
B.38.	TREATMENT OF SHORT STATURE CHILDREN WITH CHRONIC RENAL FAILURE	1.01 mln	No
B.39.	TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN HEMODIALYZED PATIENTS	23.93 mln	No
B.40.	PROPHYLAXIS OF RS VIRUS INFECTIONS	23.02 mln	No
B.41.	TREATMENT OF CHILDREN WITH PRADER-WILLI SYNDROME	1.48 mln	No
B.42.	TREATMENT OF SHORT STATURE CHILDREN WITH TURNER SYNDROME	5.08 mln	No
B.43.	TREATMENT OF HEPATITIS B IN TRANSPLANT RECIPIENTS OR PATIENTS WITH LYMPHOMAS, TREATED WITH RITUXIMAB	1.45 mln	No
B.44.	TREATMENT OF SEVERE ALLERGIC IGE-DEPENDENT ASTHMA WITH OMALIZUMAB	25.44 mln	No
B.46.	TREATMENT OF MULTIPLE SCLEROSIS AFTER FAILURE OF FIRST LINE THERAPY OR RAPIDLY PROGRESSING MULTIPLE SCLEROSIS	66.39 mln	No
B.48.	TREATMENT OF CUTANEOUS MELANOMA	46.58 mln	Yes
B.49.	ORAL TREATMENT OF IRON OVERLOAD	2.81 mln	No
B.50.	TREATMENT OF PATIENTS WITH ADVANCED OVARIAN CANCER	27.95 mln	Yes
B.52.	TREATMENT OF LOCALLY ADVANCED SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK IN COMBINATION WITH RADIOTHERAPY	2.20 mln	Yes
B.53.	TREATMENT OF WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE NEOPLASM	5.30 mln	Yes

ANNEX REF. NO	DRUG PROGRAMMES	CONTRACT VALUE [PLN]	ONCOLOGICAL
B.54.	LENALIDOMIDE IN THE TREATMENT OF PATIENTS WITH REFRACTORY OR RECURRENT MULTIPLE MYELOMA	126.40 mln	Yes
B.55.	INDUCTION OF REMISSION IN ULCERATIVE COLITIS	3.18 mln	No
B.56.	TREATMENT OF CASTRATION-RESISTANT PROSTATE CANCER	39.39 mln	Yes
B.57.	TREATMENT OF UPPER LIMB SPASTICITY AFTER STROKE WITH BOTULINUM TOXIN TYPE A	4.19 mln	No
B.58.	TREATMENT OF ADVANCED GASTRIC CANCER	7.99 mln	Yes
B.60.	TREATMENT OF TYPE I GAUCHER DISEASE	4.20 mln	No
B.61.	TREATMENT OF EARLY CHILDHOOD FORMS OF NEPHROPATHIC CYSTINOSIS	0.19 mln	No
B.64.	TREATMENT OF SHORT STATURED CHILDREN BORNED TOO SMALL COMPARED TO THE DURATION OF PREGNANCY WITH GROWTH HORMONE	1.13 mln	No
B.65.	TREATMENT OF PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA WITH DASATINIB	4.70 mln	Yes
B.62.	TREATMENT OF PRIMARY IMMUNODEFICIENCIES IN ADULT PATIENTS	22.44 mln	No
B.63.	TREATMENT OF NON-SMALL-CELL LUNG CANCER WITH AFATINIB	5.65 mln	Yes
B.66.	TREATMENT OF MYCOSIS FUNGOIDES OR SÉZARY`S DISEASE WITH BEXAROTENE	3.14 mln	Yes
B.69.	PARICALCITOL TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN HEMODIALYSIS PATIENTS	10.41 mln	No
B.67.	TREATMENT TRANSFUSIONS IMMUNOGLOBULIN NEUROLOGICAL DISORDER	49.42 mln	No
B.68.	TREATMENT OF PULMONARY ARTERIAL HYPERTENSION SILDENAFIL AND EPOPROSTENOL (PAH)	32.10 mln	No
B.70.	TREATMENT NEOVASCULAR (WET) MACULAR DEGENERATION FORMS RELATED TO AGE	107.68 mln	No
B.71.	TREATMENT OF CHRONIC HEPATITIS C INTERFERON-FREE THERAPY	458.87 mln	No
B.72.	SKIN CANCER TREATMENT WITH DABRAFENIB	30.27 mln	Yes
B.74.	TREATMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH)	8.15 mln	No
B.75.	TREATMENT ACTIVE FORM GRANULOMATOSIS VASCULITIS (GPA) OR MICROSCOPIC VASCULITIS (MPA)	1.52 mln	No
B.73.	TREATMENT NEUROGENIC DETRUSOR OVERACTIVITY	0.20 mln	No
B.47.	TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS	17.13 mln	No
B.76.	TREATMENT TYROSINEMIA TYPE 1 (HT-1)	4.53 mln	No
B.77.	TREATMENT OF REFRACTORY AND RELAPSING FORMS OF LYMPHOMA CD30 +	9.14 mln	Yes
B.78.	TREATMENT OF SYMPTOMATOLOGY OF PRIMARY IMMUNODEFICIENCIES (PIDS) IN ADULT PATIENTS WITH THE USE HUMAN NORMAL IMMUNOGLOBULIN ADMINISTERED WITH RECOMBINANT HUMAN HYALURONIDASE	0.17 mln	No
B.79.	TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA WITH OBINUTUZUMAB	0.28 mln	Yes
B.59.	TREATMENT OF MELANOMA OF THE SKIN OR MUCOUS MEMBRANES	46.42 mln	Yes
B.80.	MAINTENANCE TREATMENT OF PATIENTS WITH PLATINUM-SENSITIVE RELAPSED HIGH GRADE SEROUS EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WITH OLAPARIB	0.07 mln	Yes



REIMBURSED MEDICINES USED IN CHEMOTHERAPY

2016

List C of reimbursed medicines refers to substances used in chemotherapy. Currently, cancer is the second most important cause of Poles' deaths. Moreover, based on prognoses presented in the Polish Oncological Society report „Obecny Stan Zwalczania Nowotworów w Polsce" it can be stated, that within the next decade cancer will become the most common cause of death.

4.1. Amount of reimbursement

In accordance with NHF report for IV quarter of 2016, the planned reimbursement in chemotherapy in 2016 was PLN 0.64 billion; in fact, PLN 0.61 billion were spend, which is 94.42% of the intended plan. Table 14 presents a detailed summary for the planned and realised reimbursement expenditures in individual voivodships.

NHF expenditure on the reimbursement of medicines used in chemotherapy amounted to PLN 0.72 billion in 2016 (this amount also includes reimbursement within drug programmes in cases where the medicine is reimbursed in both drug and chemotherapy programmes).

For each calendar year from 2012 onwards, the limit group with the highest reimbursement amount was group *1035.0 Rituximab*, in which is reimbursed Mabthera.

TABLE 14.
Plan and realization of reimbursement of medicines issued for chemotherapy in individual voivodships

VOIVODSHIP BRANCH OF THE FUND	ANNUAL FINANCIAL PLAN (IN THOUSANDS PLN)	CONTRACTED FOR A GIVEN YEAR (IN THOUSANDS PLN)	REALIZED (IN THOUSANDS PLN)	PLAN REALIZATION
Dolnośląski	51 219	50 235	46 162	90.13%
Kujawsko-Pomorski	34 731	36 700	34 534	99.43%
Lubelski	38 541	33 252	35 072	91.00%
Lubuski	12 918	9 149	12 329	95.44%
Łódzki	34 344	28 289	33 873	98.63%
Małopolski	47 969	47 012	46 360	96.65%
Mazowiecki	103 676	112 185	101 271	97.68%
Opolski	15 202	11 277	14 127	92.93%
Podkarpacki	30 666	24 746	28 641	93.40%
Podlaski	23 450	21 166	21 242	90.58%
Pomorski	42 500	41 773	40 247	94.70%
Śląski	72 775	78 859	69 858	95.99%
Świętokrzyski	26 458	23 889	24 450	92.41%
Warmińsko-Mazurski	23 433	19 967	22 908	97.76%
Wielkopolski	59 498	52 009	50 425	84.75%
Zachodniopomorski	26 150	23 452	26 150	100.00%
Total	**643 530**	**613 960**	**607 648**	**94.42%**

Financial plan as of the 31st December 2016

It should be borne in mind, that the data reported by the NHF include information on sales of medicines jointly within drug and chemotherapy programmes. Mabthera is one of the medicines used in both drug and chemotherapy programmes. The following table presents 10 limit groups of medicines reimbursed within drug programmes with the highest reimbursement amount in 2016.

4.2. New substances

In 2016 the list of reimbursed medicines used in chemotherapy was extended to incorporate 2 active substances (details on Figure 33). One active substance was introduced in January and one in July.

The following table (Table 16) presents a detailed summary of substances used in chemotherapy and covered by the reimbursement, since the time when the list was created.

FIGURE 33.
Number of substances included in the reimbursement in 2016, chemotherapy

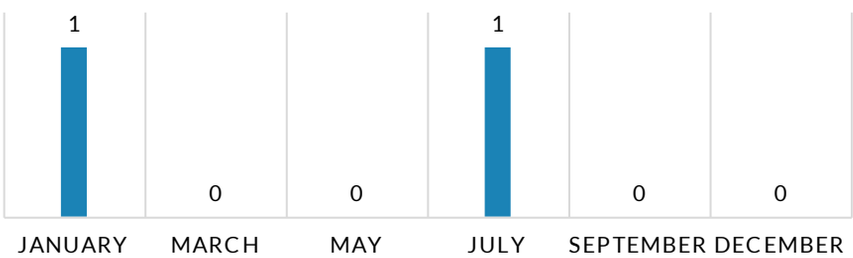


TABLE 15.
Limit groups with the highest reimbursement amount in 2016, chemotherapy

NO	GROUP CODE	GROUP NAME	AMOUNT OF REIMBURSEMENT [PLN]
1	1035.0	Rituximabum	225.30 million
2	1043.1	Erythropoiesis stimulants - darbepoetin	42.75 million
3	1026.0	Somatostatin analogues	40.87 million
4	1019.0	Fulvestrant	35.75 million
5	1045.0	Granulopoiesis-stimulating agents	33.82 million
6	1118.0	Antineoplastic agents - antimetabolites - pyrimidine analogues - azacitidine	30.83 million
7	1054.0	Bortezomib	27.25 million
8	1014.3	Liposomal doxorubicin, pegylated	25.42 million
9	1053.0	Anagrelide	25.14 million
10	1034.0	Pemetrexed	22.41 million

Medicines from limit groups 1034.0, 1035.0 and 1043.1 are also reimbursed within drug programmes, thus the reimbursement amount refers to consumption in both, chemotherapy and drug programmers

TABLE 16.
New active substances covered by reimbursement within the list of reimbursed medicines used in chemotherapy in 2016

DATE OF ENTRY	NUMBER OF NEW SUBSTANCES	SUBSTANCES
January	1	mitoxantrone
July	1	crisantaspase

MECHANISMS IMPLEMENTED SINCE THE BEGINNING OF 2012

2016

In the new Reimbursement Act it has been established the way of pricing medicines and the payment level for policyholders; medicines with similar action have been combined into limit groups, the principle of prices reduction was introduced in case of reimbursement of first equivalents as well as the expiration of market exclusivity, also has been specified the duration of time for issuing successive reimbursement decisions between which renegotiations with the Economic Committee take place. All these developments influence the price formation of medicines, the state expenditure and the level of payments for patients.

A number of regulations introduced in the new Reimbursement Act affects the size of the limit on medicine financing. Limit groups with the largest reduction in the net sale price per LDD of the basis for the limit, as much as by 81% are groups *166.1 Antiepileptic drugs for oral administration - levetiracetam - solid formulations* and *191.0 Drugs used in amyotrophic lateral sclerosis - riluzole*. The following table (Table 17) presents 10 groups with the strongest declines in sales price per LDD of the package determining the basis for the limit.

5.1. First equivalent

In accordance with the definition in the new Reimbursement Act the equivalent is, in case of:

a. medicine – is a medicine containing the same active substance and with the same clinical indications and the same route of administration without differences in pharmaceutical form,

TABLE 17.
Limit groups with the largest reduction in the net sale price per LDD of the basis for the limit, from the moment the group was set-up to November 2016

GROUP CODE	GROUP NAME	DATE OF CREATION OF THE LIMIT GROUP	NET SALE PRICE PER LDD OF THE BASIS FOR THE LIMIT [PLN]		
			FIRST MONTH OF REIMBURSEMENT	01.11.2016	% PRICE REDUCTION
166.1	Antiepileptic drugs for oral administration - levetiracetam - solid formulations	01.01.2012	13.1393	2.4599	81%
191.0	Drugs used in amyotrophic lateral sclerosis - riluzole	01.01.2012	35.1743	6.6504	81%
220.3	Moisture regulating dressings with additional components	01.01.2012	0.2982	0.0727	76%
146.3	Drugs used in bone diseases - bisphosphonates for parenteral administration - zoledronic acid	01.09.2013	483.7891	118.9646	75%
166.2	Antiepileptic drugs for oral administration - levetiracetam - liquid formulations	01.01.2012	14.5613	3.7599	74%
112.1	Antifungals for systemic use - triazole derivatives - voriconazole	01.09.2015	215.5083	59.8680	72%
178.7	Antipsychotics - aripiprazole	01.01.2012	14.7837	5.1923	65%
220.7	Antimicrobial dressings containing silver	01.01.2012	0.2190	0.0790	64%
149.2	Opioid analgesics – morphine for parenteral administration	01.01.2012	8.4533	3.3588	60%
46.0	Lipid modifying agents - HMG CoA reductase inhibitors	01.01.2012	0.7035	0.2805	60%

b. foodstuff intended for particular nutritional uses – is a foodstuff intended for particular nutritional uses with the same or similar composition, usage or preparation,,
c. medical device – is a medical device having the same intended use and properties.

According to new Reimbursement Act, reimbursement of the first equivalent implies the determining of its official selling price, which must not be higher than 75% of the official selling price of the only equivalent previously reimbursed in that indication (taking into account the number of DDDs in the unit package). As a consequence, generic medicines will be cheaper so that public spending can be reduced. In addition, if the package determined by a complement to a certain share of a group is more expensive than the first equivalent, the limit in the group shall be based on the first equivalent. In case of reimbursement of additional equivalents, the limit base cannot be greater than the wholesale price for DDD of the first equivalent.

In 2016 the outpatient list covered 15 first equivalents, in drug programmes 6 first equivalents, whereas in chemotherapy 3 first equivalents. (Figure 34)

The following table presents the list of first equivalents. (Table 18)

As an example, the analysis will be performed on the limit group *199.2 Inhaled long-acting beta-2-adrenergic agonists - combinations with medium-dose corticosteroids*. In March 2013 two new products have been added to the list: Salmex i Asaris, which are the first equivalents of Seretide (fruktykazon + salmeterol) and automatically became the base of the limit in the group (following the principle of establishing the financing limit at the wholesale price for DDD of the first equivalent reimbursed in a given indication, if it is lower than the wholesale price for LDD up to 15% of a complementary medicine), thus lowering the financing limit in this group. Then, at January 2016 another equivalent was added to the group: Bufomix Easyhaler, this time it is the first equivalent of Symbicort Turbuhaler (budezonid + formoterol). Given that Asaris i Salmex complemented up to 15% share of the group, a wholesale price for DDD of Bufomix Easyhaler was higher, thus in this situation the limit base remained unchanged (Figure 36, p. 31).

FIGURE 34.
Number of of first equivalents broken down by reimbursement lists

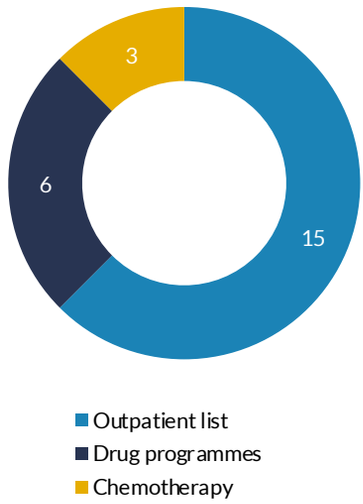


FIGURE 35.
Number of first equivalents broken down by subsequent announcements in 2016

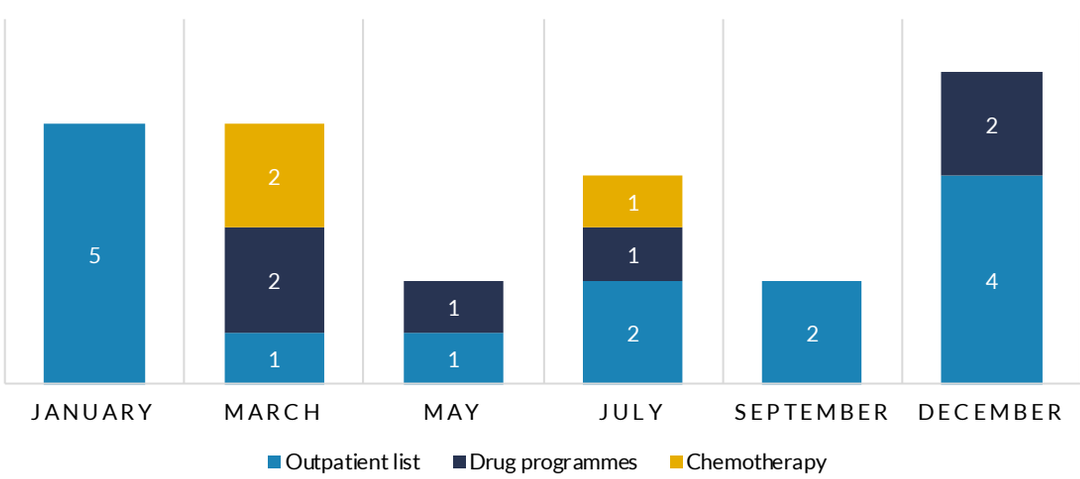


TABLE 18.
First equivalents in 2016

DATE OF ENTRY	DRUG NAME	SUBSTANCES	LIMIT GROUP	REIMBURSEMENT INDICATION
		Outpatient list		
January	Bufomix Easyhaler	Budesonidum + Formoterolum	199.2	Asthma, chronic obstructive pulmonary disease, eosinophilic bronchitis
January	Bufomix Easyhaler	Budesonidum + Formoterolum	199.3	Asthma, chronic obstructive pulmonary disease, eosinophilic bronchitis
January	Ceglar	Valganciclovirum	116.0	Cytomegalovirus infection in patients undergoing parenchymal organ transplantation - prophylaxis after hospitalization associated with transplantation up to 110 days after transplantation, Cytomegalovirus infection in patients undergoing kidney transplantation - prophylaxis after hospitalization associated with transplantation up to 200 days after procedure
January	Envarsus	Tacrolimusum	139.0	Condition after vascularized organ or bone marrow transplantation
January	Furaginum Adamed	Furaginum	108.0	The treatment of acute or recurrent, uncomplicated lower urinary tract infections due to susceptible strains of Escherichia coli
March	Mensinorm	Menotropinum	69.1	Controlled ovarian hyperstimulation in patients below 40 years of age in order to achieve the development of multiple follicles within assisted reproductive technology, promising to get the correct response to stimulation of ovulation (follicle stimulating hormone - FSH less than 15 mIU / ml in the 2-3 day cycle or Anti-Müllerian Hormone - AMH above 0.7 ng / ml (according to II standard)), with no evidence of earlier, insufficient responses to stimulation of ovulation, and without recurrent miscarriages with the same partner - a refund for 3 cycles
May	Karbostad	Oxcarbazepinum	160.1	Treatment-refractory epilepsy
July	Reseligo	Goserelinum	129.0	Malignant tumors - breast cancer and endometrial cancer, malignant tumors - Prostate cancer, inhibition of pituitary function in patients under the age of 40 years old, in preparation for controlled ovarian hyperstimulation - refund to 3 cycles, Malignant tumors - Prostate cancer
July	Ursocam	Acidum ursodeoxycholicum	245.0	Primary biliary cirrhosis in the early stages of the disease
September	Metmin	Mometasonum	196.0	The treatment of seasonal allergic or perennial allergic rhinitis and nasal polyps in adults
September	Momester	Mometasonum	196.0	The treatment of seasonal allergic or perennial allergic rhinitis and nasal polyps in adults
November	Bixebra	Ivabradinum	31.1	Chronic heart failure NYHA classes II - IV, with impaired systolic function in patients with ECG confirmed sinus rhythm and heart rate >=75 beats per minute, in combination with standard treatment, including beta-blocker or if beta-blocker therapy is contraindicated or not tolerated
November	Neoparin	Enoxaparinum natricum	22.0	Prophylaxis of venous thromboembolic disease, treatment of deep vein thrombosis, acute coronary syndrome, angina pectoris, prevention of thrombus formation in extra corporeal circulation during haemodialysis
November	Oprymea	Pramipexolum	170.0	Treatment of the signs and symptoms of idiopathic Parkinson's disease in adults, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations)
November	Propranolol Accord	Propranololum	39.0	Angina pectoris, hypertension, long-term prophylaxis against myocardial reinfarction after recovery from acute myocardial infarction, hypertrophic obstructive cardiomyopathy, essential tremor, ventricular and supraventricular cardiac arrhythmia, hyperthyroidism and thyrotoxicosis, phaeochromocytoma, migraine, prophylaxis of upper gastrointestinal bleeding in patients with portal hypertension and oesophageal varices

DATE OF ENTRY	DRUG NAME	SUBSTANCES	LIMIT GROUP	REIMBURSEMENT INDICATION
Drug programmes				
March	Pemetreksed Adamed	Pemetreksedum	1034.0	drug programmes
March	Pemetrexed Sandoz	Pemetreksedum	1034.0	drug programmes
May	Cinacalcet Accord	Cinacalcetum	1058.0	drug programmes
July	Benepali	Etanerceptum	1050.2	drug programmes
November	Lamivudine Mylan	Lamivudinum	1067.0	drug programmes
November	Remurel	Glatirameri acetas	1061.0	drug programmes
Chemotherapy				
March	Pemetreksed Adamed	Pemetreksedum	1034.0	chemotherapy
March	Pemetrexed Sandoz	Pemetreksedum	1034.0	chemotherapy
July	Mitoxantron Accord	Mitoxantronum	1141.0	chemotherapy

As an another example, we have analysed the case of limit group *129.0 Antineoplastic and immunomodulating agents - gonadotropin releasing hormone analogues*. In November 2012 Decapeptyl Depot have been added to the list as the first equivalent of Diphereline SR (triptorelin) and it automatically became the base for the limit in the group (following the principle of establishing the financing limit at the wholesale price for DDD of the first equivalent reimbursed in a given indication, if it is lower than the wholesale price for LDD up to 15% of a complementary medicine), thus lowering the financing limit in this group. Then, at July 2016 another equivalent was added to the group: Reseligo, this time it is the first equivalent of Zoladex (goserelin). Given that the wholesale price for DDD of Reseligo was less than the price of the package complementing 15% of turnover of a group, it became the medicine constituting the basis of the limit in the group (Figure 37).

5.2. Market exclusivity

According to the Pharmaceutical Law, market exclusivity means that it is not permissible to place on the market an equivalent drug up to 10 years after the date of issuing a first marketing authorisation for a reference pharmaceutical product in a Member State of the European Union or a member state of the European Free Trade Agreement.

According to the new Reimbursement Act, the period of validity of the decision on reimbursement should not exceed expiration date of the time period of market exclusivity, and additionally after its expiration, official selling price in the next reimbursement decision must not be higher than 75% of the official net selling price effective before the expiration date of market exclusivity.

The concept of market exclusivity, derived from European legislation (Regulation 726/2005 and Directive 2004/27) applies to medicines submitted to registration after 20 November 2005 (in case of medicines registered under the central procedure) and after 30 October 2005 (in case of other medicines). As a consequence, the

FIGURE 36.
Limit base in the group 199.2 between 2012–2016

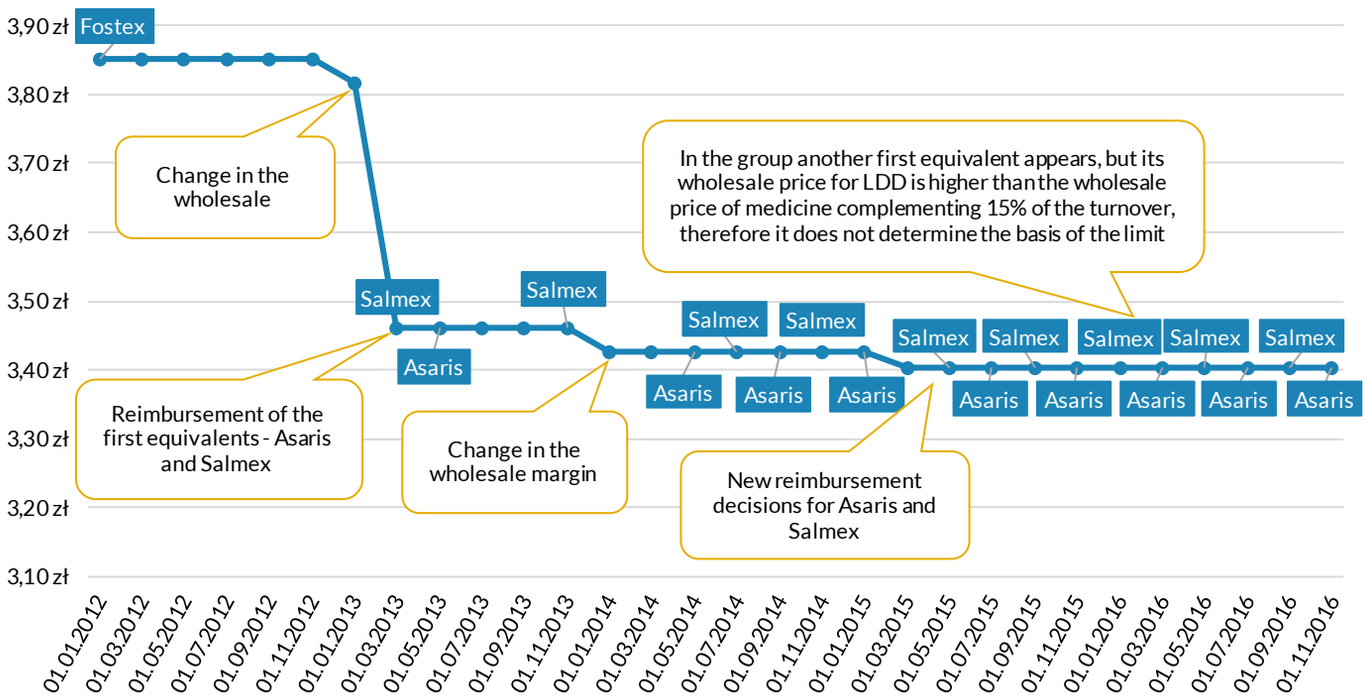
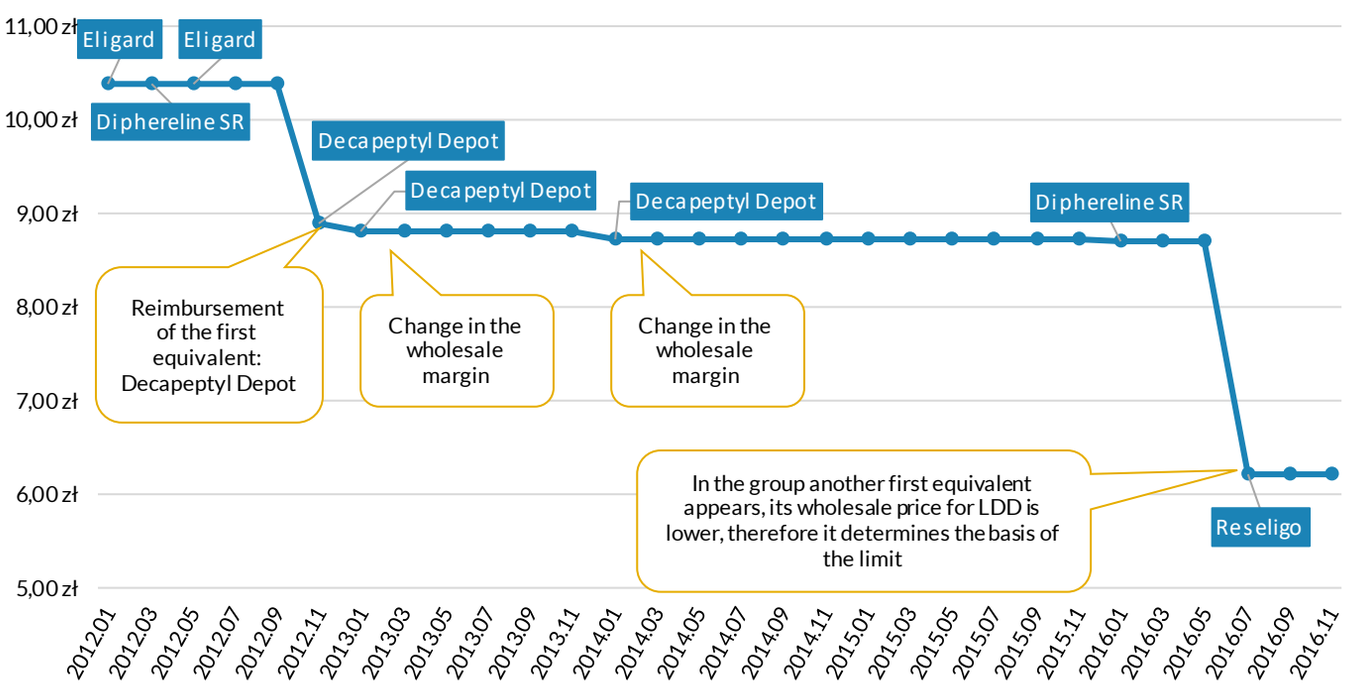


FIGURE 37.
Limit base in the group 129.0 between 2012–2016



first market exclusivities expired in 2015 and only then did the new Reimbursement Act on the reduction of the official selling price of the drug have been applied.

For part of the packages, together with new decision issued after the expiry of the period of market exclusivity, the official prices are reduced by 25%, as in the case of Sprycel (dasatynibum) (Table 19).

However, for some preparations, in order to escape price reductions, before the expiration of market exclusivity, requests for price increases were submitted. Companies were getting a new decision, in which the official selling price of their medicine was higher. After this decision had expired, in accordance with the Reimbursement Act [1], the price of that medicine was reduced again. In case of preparations Myozyme (alglucosidasum alfa) and Evoltra (clofarabinum) official package price was changed only in one of the announcements. Official selling price of Nexavar (sorafenib) after the expiration of the market exclusivity period slightly decreased relative to the initial price.

It should be emphasized, that the price of medication should be increased by about 33%, so that after a reduction of the already increased price by 25% obtain the initial price. This was probably forgotten in case of Exjade (deferazyroxum) preparation, which price was increased only by 25%, resulting in lower initial price of this medicine after market exclusivity had expired.

As a consequence of expiration date of market exclusivity, the second decision on Naglazyme (galsulfaseum) reimbursement was in force until the end of December 2015. In this case, no additional reimbursement decision has been issued and in January 2016 the package has been taken off the list of reimbursed medicines. Reimbursement for this preparation was once again granted a as late as in January 2016 with the same official selling price which was before the expiration of market exclusivity, but it had to go through evaluation by the Agency for Health Technology Assessment and Tariff System.

5.3. Duration of reimbursement decision

In accordance with the Reimbursement Act the first decision was issued for a period of 2 years, the second one also for 2 years, the third one for 3 years, and the fourth and later will be issued for a period of 5 years (Figure 38).

TABLE 19.
Packages, for which prices were reduced by 25%

DOSE, PACKAGE	EAN CODE	RESPONSIBLE ENTITY	OFFICIAL SELLING PRICE [PLN]	
Sprycel (dasatynibum)			10-2016	11-2016
50 mg, 60 tab.	5909990621354	BRISTOL-MYERS SQUIBB PHARMA EEIG	14 009.72	10 507.27
20 mg, 60 tab.	5909990621323	BRISTOL-MYERS SQUIBB PHARMA EEIG	5 603.88	4 202.91
80 mg, 30 tab.	5909990818631	BRISTOL-MYERS SQUIBB PHARMA EEIG	11 207.76	8405.81
140 mg, 30 tab.	5909990818655	BRISTOL-MYERS SQUIBB PHARMA EEIG	19 613.61	14 710.17
100 mg, 30 tab.	5909990671601	BRISTOL-MYERS SQUIBB PHARMA EEIG	14 009.72	10 507.27

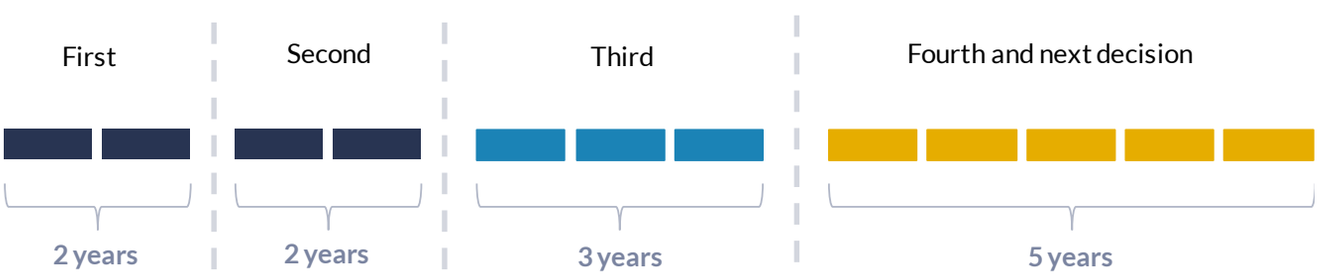
TABLE 20.
Packages, for which the price was increased before the expiry of the period of market exclusivity

DOSE, PACKAGE	CODE EAN	RESPONSIBLE ENTITY	OFFICIAL SELLING PRICE [PLN]			
Myozyme (alglucosidasum alfa)			**12-2015**	**01-2016**	**02-2016**	**03-2016**
50 mg/vial., 1 vial	5909990623853	GENZYME EUROPE B.V.	1 892.16	2 522.88	2 522.88	1 892.16
Evoltra (clofarabinum)			**02-2016**	**03-2016**	**04-2016**	**05-2016**
20 mg, 1 vial	5909990710997	GENZYME EUROPE B.V.	6 905.52	9 207.36	9 207.36	6 905.52
Nexavar (sorafenib)			**04-2016**	**05-2016**	**06-2016**	**07-2016**
200 mg, 112 tab.	5909990588169	BAYER PHARMA AG	15 660.00	20 879.64	20 879.64	15 659.73
Exjade (deferazyroxum)			**06-2016**	**07-2016**	**08-2016**	**09-2016**
250 mg, 28 tab.	5909990613021	NOVARTIS EUROPHARM LIMITED	1 508.97	1 886.21	1 886.21	1 414.65
500 mg, 28 tab.	5909990613045	NOVARTIS EUROPHARM LIMITED	3 017.91	3 772.39	3 772.39	2 829.29
125 mg, 28 tab.	5909990613007	NOVARTIS EUROPHARM LIMITED	754.48	943.1	943.1	707.32

TABLE 21.
Prices of Naglazyme (galsulfaseum) between December 2015 and March 2016 [PLN]

DOSE, PACKAGE	CODE EAN	RESPONSIBLE ENTITY	12-2015	01-2016	02-2016	03-2016
1 mg/ml, 1 vial a 5 ml	5909990614745	BIOMARIN EUROPE LIMITED	7001.64	-	-	7001.64

FIGURE 38.
Duration of subsequent reimbursement decisions



Valid in 2016.

First reimbursement decisions were binding until December 2013, the second ones remained in force from January 2014 to December 2015, and in January 2016, for medicines reimbursed since 2012 third reimbursement decisions were issued, valid until December 2018.

From among packages of medicines reimbursed since the beginning of the new Reimbursement Act, prices of more than half of the packages (1 347) were lowered when a third refund decision was issued, 876 packages remained unchanged, and no subsequent reimbursement decision has been issued for 163 packages (Figure 39). Among packages with price reduction at 83%, there were packages whose ex-factory price for LDD was higher than ex-factory price for LDD based on the limit. If we look at the retail price and financing limits it turns out, that among packages with 81% reduction in prices there were packages, whose retail price was higher than the financing limit.

Presented above statistics regarding the second and third reimbursement decisions demonstrate, that prices are lowered predominantly when the patient's payments are high, and in addition to the payment calculated against the financing limit, it must pay the difference in retail price and funding limit. Lack of extension of the decision usually applies to medicine packages with insignificant sales, and then companies resign from applying for their subsequent reimbursement.

The greatest changes can be observed in limit groups with a large number of packages used in indications for large populations, as in the case of group *45.0 Angiotensin II antagonists - single-agent preparations* and combined preparations, existing since the beginning of the new Reimbursement Act. Currently (based on the announcement effective since 1st November 2016) in the group are 284 packages (13 active substances or their combinations). In January 2012 group had 71 packages, and within five years of reimbursement, 253 new packages have been added, and 40 have been removed. Public payer's expenditures on medicines in this group increased from PLN 221 million in 2012 to PLN 317 million in 2016. (Figure 40)

In November 2012 and January 2013 the first equivalents appeared in the group, lowering the financing limit in this limit group. The figure below shows how LDD financing limit in the analysed group has evolved. (Figure 41, p.45)

The situation in the limit group 45.0 was analysed, considering only drugs reimbursed from the beginning of the Act, at the time of issuing third reimbursement decisions (January 2016). For the majority of medicines in the group, in both the second and third reimbursement decisions prices of medicines were reduced (Figure 42).

By comparing patient payments for medicines from the last announcement of the second decision with the first announcement of the third decision, it can be seen that the number of packages with lower prices increased as a consequence of subsequent reimbursement decisions. In addition, the largest increases in the number of packages qualifying for particular ranges of patient payments can be seen in case of low patient payments, not exceeding PLN 20. Medicines in the analysed limit group are used chronically, thus a patient has to constantly purchase them, so it is expected that he prefers cheaper medicines to reduce recurrent expenditure on the treatment. As a large number of packages is available in the group, during renegotiations pharmaceutical companies decided to lower medicine prices in order to make the prices more attractive for patients and to increase drug sales (Figure 43, p.45).

FIGURE 40.
NHF expeditures on medicines in group 45.0

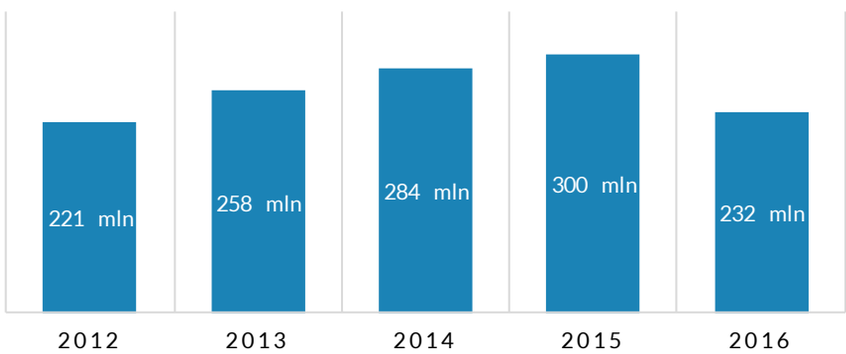


FIGURE 39.
Statistics on changes during issuing a third reimbursement decision, for medicines reimbursed since the beginning of the new Reimbursement Act (for outpatient list since 1.01.2012, for inpatient healthcare since 1.07.2012)

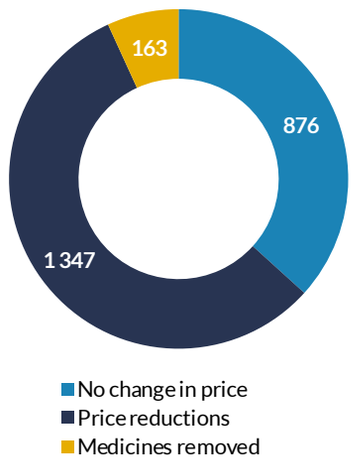


FIGURE 42.
Statistics on changes in group 45.0 during issuing second and third reimbursement decisions, for medicines reimbursed since the beginning of new Reimbursement Act (for outpatient list since 1.01.2012, for inpatient healthcare since 1.07.2012)

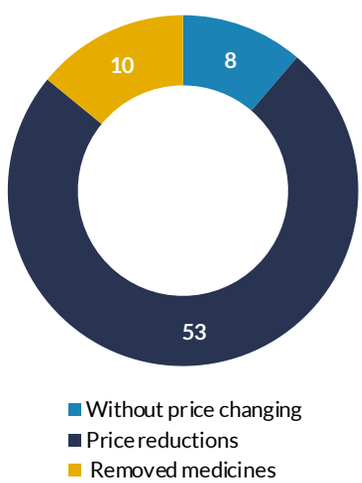
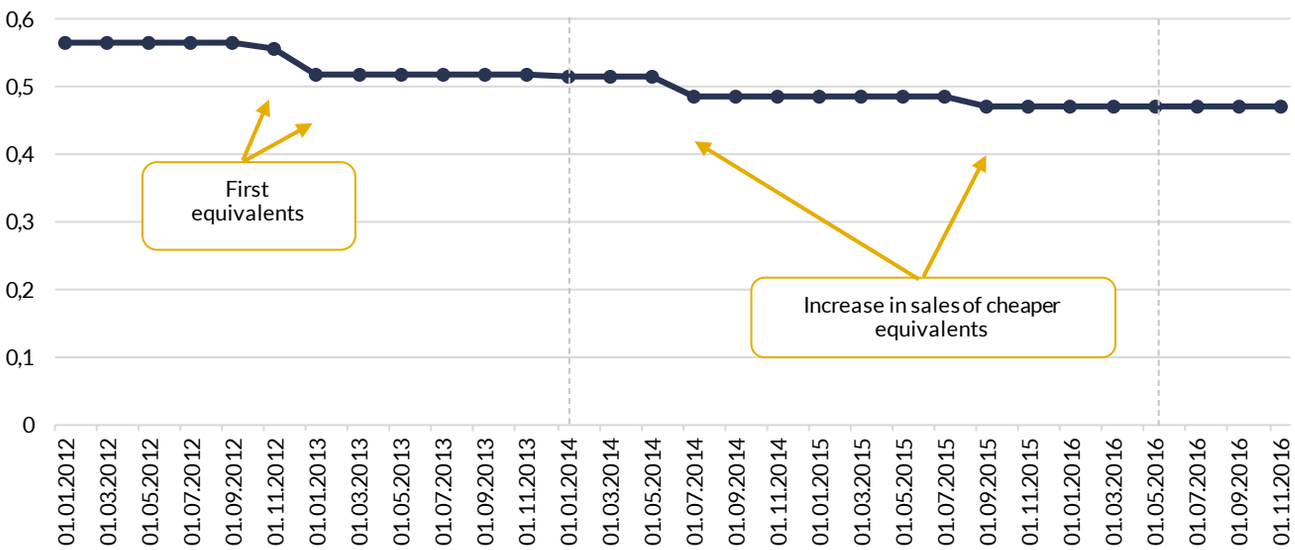
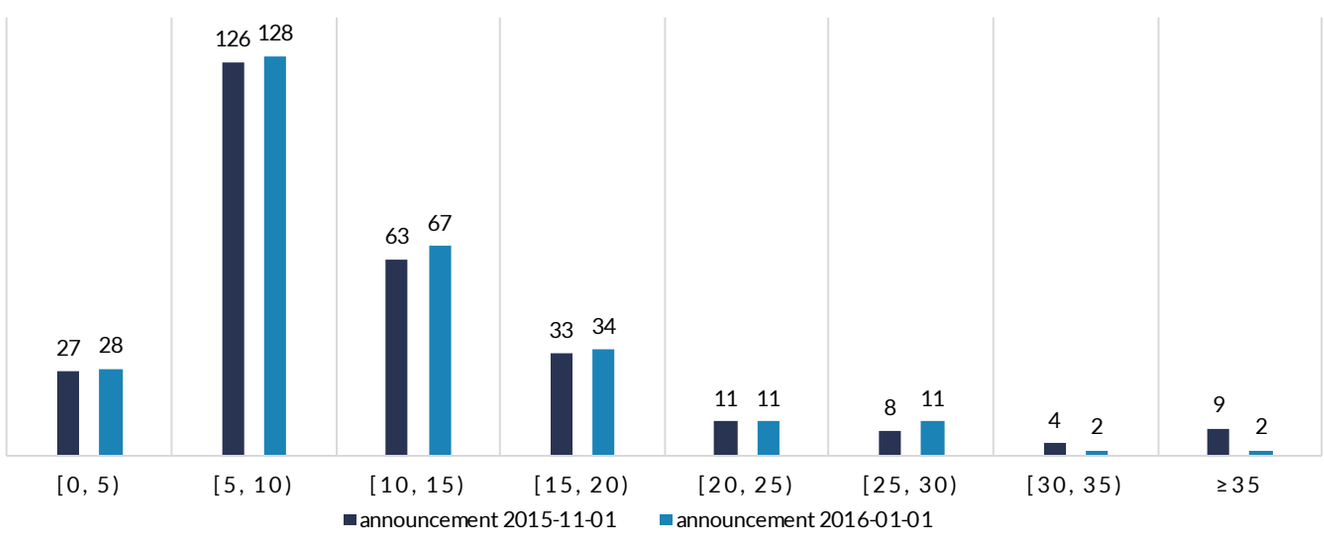


FIGURE 41.
Financing limit for LDD in group 45.0 between 2012–2016



The dotted line marks the moments of the second and third reimbursement decision for packages eligible for reimbursement in January 2012.

FIGURE 43.
Number of packages with patient payment within a given price range, in November 2015 and January 2016



5.4. Types of payment

According to the new Reimbursement Act, patients may receive the preparation free of charge for medicines used in drug programmes me or where its efficacy has been proven in the treatment of malignant cancer, mental disorder, intellectual disability or developmental disorder, or an infectious disease with a serious epidemic risk to the population. Medicines used for less than 30 days, whose cost of applying the funding limit for a patient at 50% fee would not exceed 30% of the minimum wage, are eligible for

payment at 50%, otherwise to a lump sum payment. Preparations that require to be used for more than 30 days, where the monthly cost of use for patient at 30% of the financing limit would exceed 5% of the minimum wage, are eligible for lump sum payment, otherwise they are entitled to payment at 30%. In addition, all reimbursed medicines with a lump sum payment before the new Reimbursement Act came into force, i.e. before 01.01.2012 and their equivalents, retain this payment category regardless of cost incurred by patient. The largest number of packages is reimbursed with a lump sum payment and a co-payment of 30%, significantly less is reimbursed with a co-payment of 50% and free of charge (Figure 44).

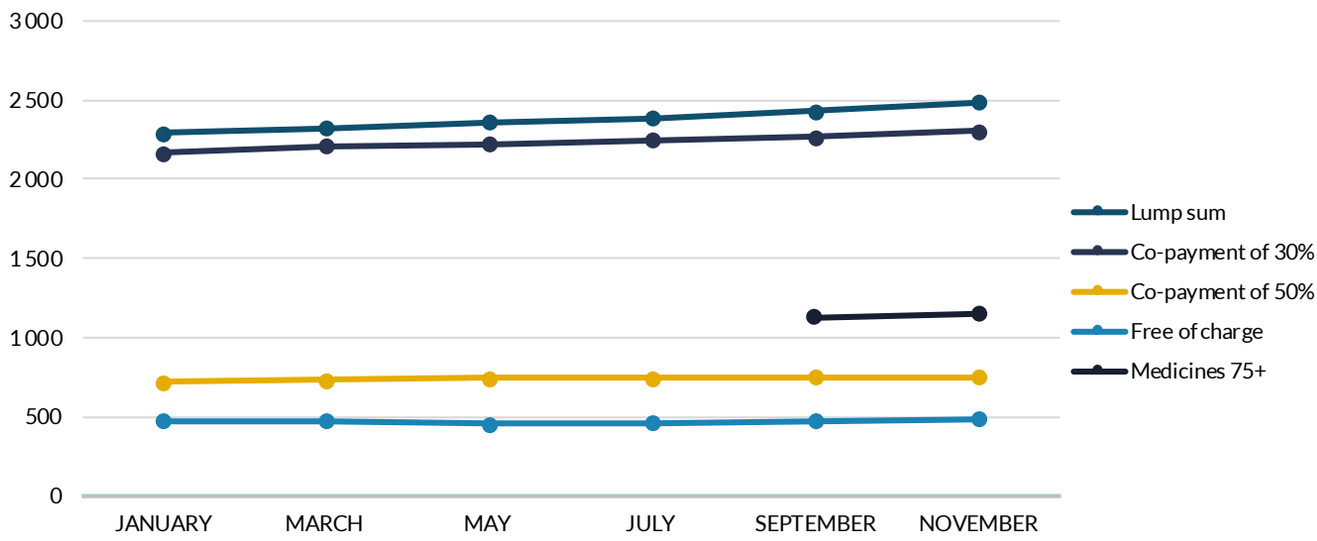
Since September 2016 a new type of payment has been available for seniors, medicines 75+. Namely, patients over the age of 75 are given free of charge medicines from a special list, published together with the reimbursement announcement (details in the next Chapter 5.5).

5.5. Free of charge medicines for seniors

Since September 2016, a list of medicines issued free of charge to patients over 75 years of age has been issued. The list is published along with a reimbursement announcement and comprises medicines used primarily in the treatment of age-related diseases (mainly chronic diseases such as cardiovascular diseases, Parkinson's disease and osteoporosis). Part of expenses incurred by patient on medicines is paid from the state budget, which will allow the patient to receive these medicines free of charge. The subsidy will be transferred from the Minister of Health to the President of NHF. In the first full year of validity of the regulation (2017 r.) PLN 564 million will be allocated for this purpose. This amount will be increasing in the following years (details regarding the amount of financial support from state budget are presented in the first part of the report – Figure 2, page 8).

List 75+ includes medicines which, on the basis of the reimbursement announcement, are issued to patients with a lump sum payment and 30% or 50% co-payment. The

FIGURE 44.
Number of reimbursed packages in 2016 broken down by type of payment, with which patients can purchase medicines in pharmacy



first list (from 1st September 2016) included 1 129 preparations containing 68 active substances with 8 molecules paid on a lump sum basis. The following list, in force since 1st November 2016 included 1 149 preparations, of which 28 packages have not been reimbursed before. Meanwhile, 8 packages included in the previous 75+ list were removed due to the fact that they were not included in the November reimbursement announcement. No new molecule was added to the list, so the number of active substances remained unchanged.

In order to examine how the launch of a list of free of charge medicines for seniors (list S) since September 2016 has influenced the sale of reimbursed medicines, drugs used in the treatment of osteoporosis and glaucoma have been analysed.

5.5.1. MEDICINES FOR SENIORS IN THE TREATMENT OF OSTEOPOROSIS

Osteoporosis is a skeletal disease leading to bone fractures, which can occur even after a minor injury. Typically, it affects the spine, forearm bones and femoral neck, but also can be present in other locations. Excessive bone susceptibility to damage in osteoporosis results from decreased bone mineral density and deterioration of its structure and quality.

Osteoporosis predominantly occurs as the **primary osteoporosis**, being a consequence of aging of the skeletal system. It develops in women after menopause and in elderly men. Decrease in bone mineral density is an inevitable process related to ageing, starting as early as about 40 years in women and 45 years in men. However, there are many factors that can accelerate its progress. Some of them can be prevented by changing the lifestyle.

Less common is **secondary osteoporosis**, which is caused by other diseases or the use of certain drugs. This form of osteoporosis affects people of all ages.

Osteoporosis is a very common disease among elderly people. It is affecting every third woman after menopause. For 50 year old women, the risk of bone fracture due to osteoporosis for the rest of their lives is about 40%, whereas for men the risk is 13-22%. [4]

Osteoporosis is a chronic disease that often develops asymptomatically [5]. The aim of osteoporosis treatment is to prevent bone fractures and consequent complications. Unfortunately, most medicines should be taken for a long time (usually several years), and prophylactic efforts should be taken systematically until the end of life.

Medicines reducing the risk of bone fractures. In the treatment of osteoporosis, drugs from several groups are used. They are of different functions (some of them reduces bone loss, the others enhance bone regeneration), and different activities depending on sex, age and other factors. In the prevention of fractures, only drugs with proven efficacy should be used. The mere increase of bone mineral density, as determined in the densitometric test, is not always associated with the increase of its mechanical resilience. [4]

Medicines used for the treatment of osteoporosis:

- bisphosphonates (alendronate, risedronate, zoledronate, ibandronate)
- raloxifene
- teriparatide
- strontium ranelate
- parathormone
- calcitonin
- denosumab
- hormone replacement therapy (HRT) [4, 6]

In Poland, there are reimbursed antiosteoporotic drugs from biphosphonates group (alendronate, ryzedronate) and calcitonin, and since the last year also the newest anti-osteoporotic drug - denosumab. [6]

At present, reimbursed medicines used for the treatment of osteoporosis are from limit groups

- *147.0 Drugs used in bone diseases - oral bisphosphonates - alendronic acid and risedronic acid*
- *231.0 Drugs used in bone diseases - monoclonal antibodies - denosumab.*

At this time, the limit group *147.0* comprises 13 medicines, whereas only one drug belongs to the limit group 231.0. In order to determine the impact of program 75+ on drug sales, we will compare the change in the reimbursement amount intended for drugs from above mentioned limit groups and sales of LDD of these drugs.

By comparing the situation between January 2012 and December 2016 r. one can see a significant difference in the size of the amount incurred for the reimbursement on medicines from studied groups. For limit group *147.0* the amount of reimbursement has been following a downward trend over the last 5 years, whereas in the limit group *231.0* a significant increase is visible during first three months, from PLN 0 in 2012 to almost PLN 1.6 million at the end of 2016. In both groups, since September 2016 (that is, since the introduction of list S) the amount for sales of reimbursed medicines has increased. For limit group *231.0* this increase is more pronounced. (Figure 45, Figure 46)

When analysing the amount of the reimbursement broken down by the type of payment (Figure 47, Figure 48) it can be noticed, that despite the fact that there was an increase in sales of drugs from the analysed groups after launching free medicines for patients 75+, the share of packages sold at a payment for 75+ was much lower than the share of packages sold from the second payment category. This suggests that patients over 75 years of age are not primary consumers of medicines in this group. The increase in the reimbursement amount, which occurred for the limit group *147.0* can be attributed to the introduction of program 75+, as the reimbursement amount significantly decreased before the launch of the program.

In the limit group *147.0* in September there was a large surge in LDD sales compared to previous month, but in the following month it was rather modest compared to the period before program deployment. In case of the limit group *231.0* since 2016 a significant increase in drug sales (faster than the growth trend before the inclusion of medicine in the list of free medicines for seniors) can be observed, which continued for several consecutive months, although the share of medicines with 75+ payment

FIGURE 45.
Amount of reimbursement incurred on medicines from the limit group 147.0.

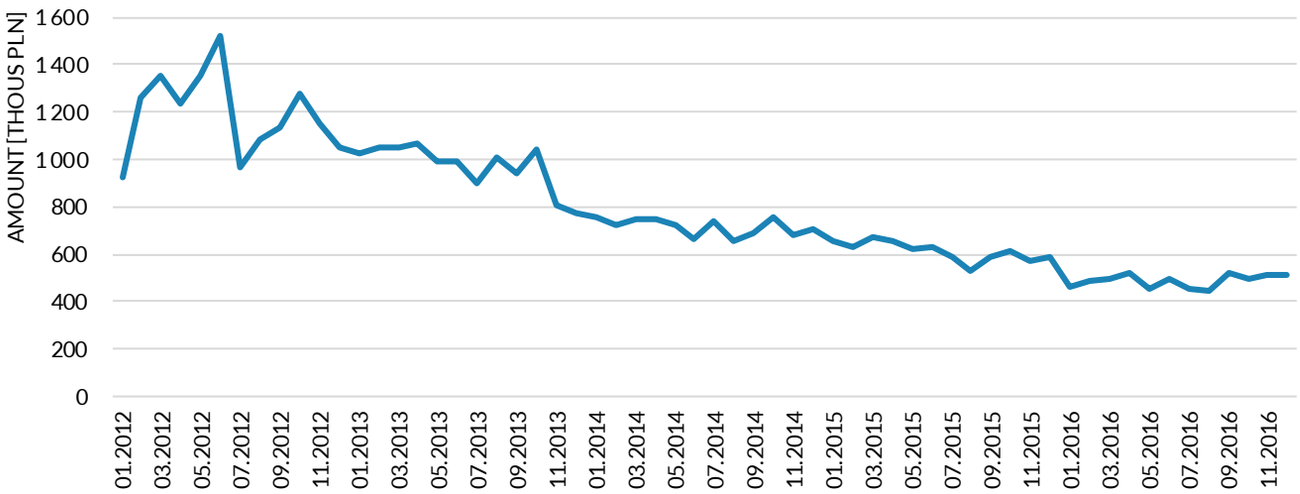
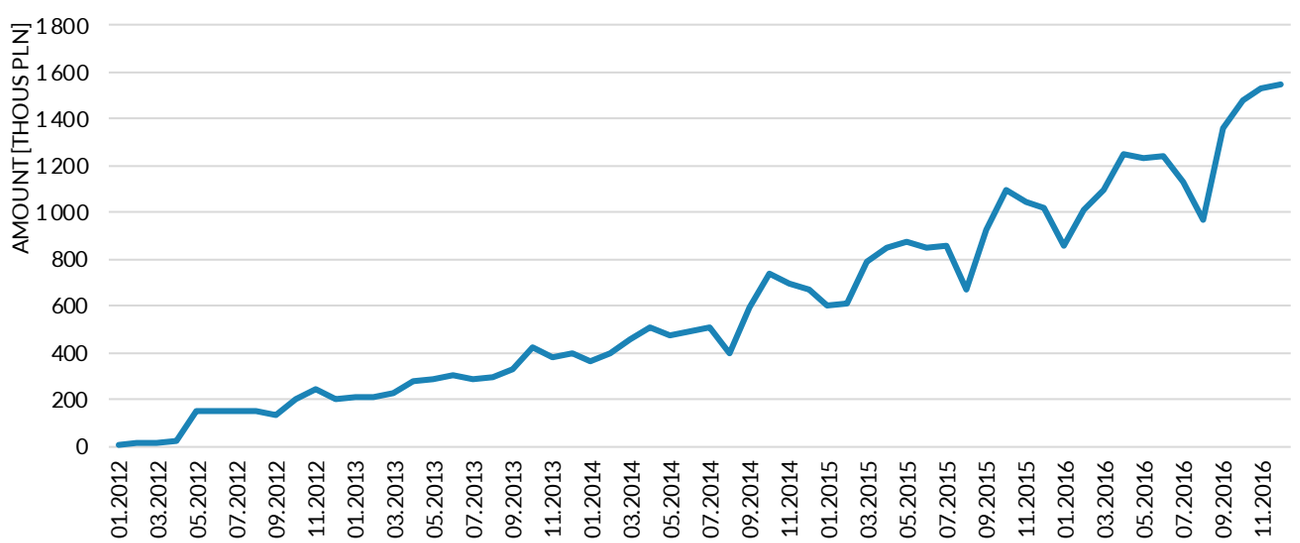


FIGURE 46.
Amount of reimbursement incurred on medicines from the limit group 231.0.



was small. This difference in the impact on drug sales between studied groups probably is related to the fact, that patient payment (excluding payments for seniors) for 30 LDD, i.e. the two-week cost of treatment, for drugs in group *147.0* amounts between PLN 2.69 and PLN 6.06, whereas in group *231.0* amounts PLN 41.85. Therefore, the establishment of a list of free medicines for seniors in case of limit group *231.0* has led to an increase in the sales of this medicine, as patients do not incur such a large cost for this medicine. In the case of the limit group *147.0* due to low level of patient payments, such strong increase in consumption of these drugs after inclusion on the list of free medicines for seniors was not observed.

When analysing the proportion of doses given to seniors free of charge to the total number of packages sold, it can be seen that they do not constitute any significant share and amount to only about 9%. Therefore, it can be concluded that the introduction of program 75+ did not have any significant impact on the increase in the sale of medicines from analysed limit groups.

FIGURE 47.
Reimbursement amount broken down by the type of payment for a limit group 147.0.

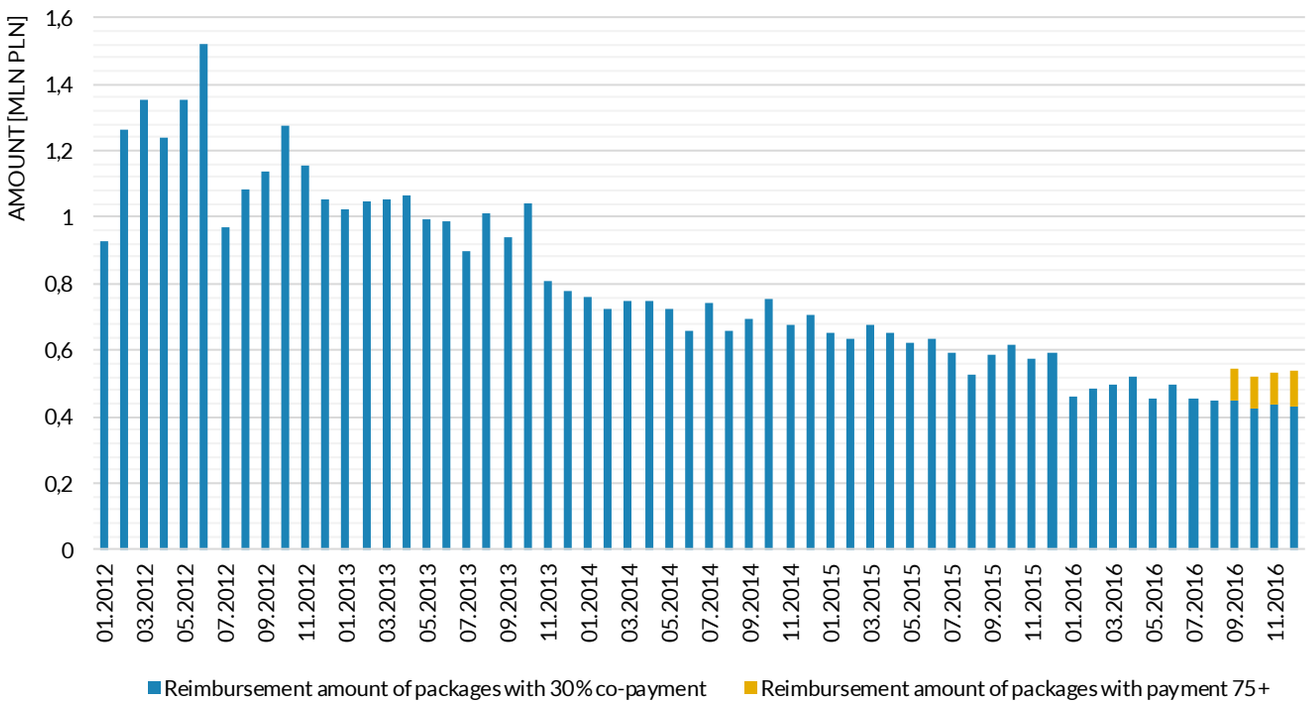


FIGURE 48.
Reimbursement amount broken down by the type of payment for a limit group 231.0.

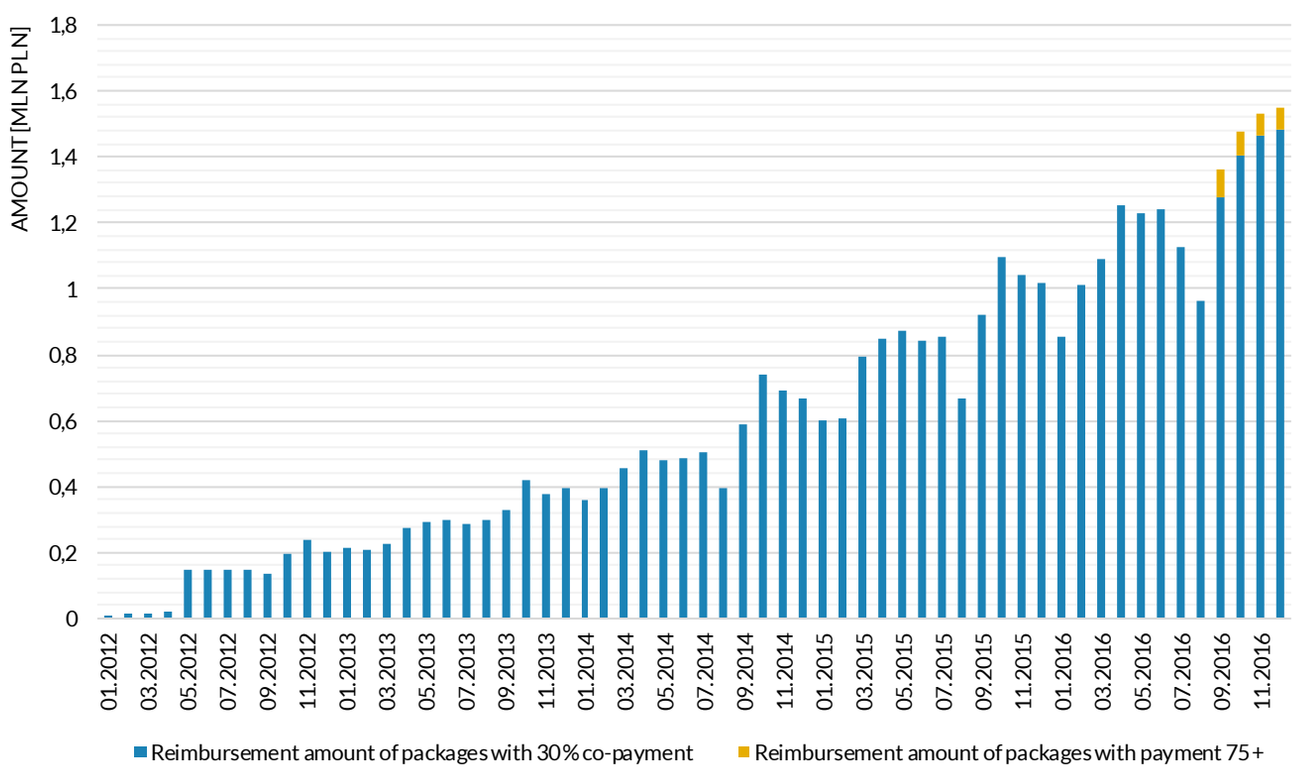


FIGURE 49.
LDD sales broken down by the type of payment for the limit group 147.0.

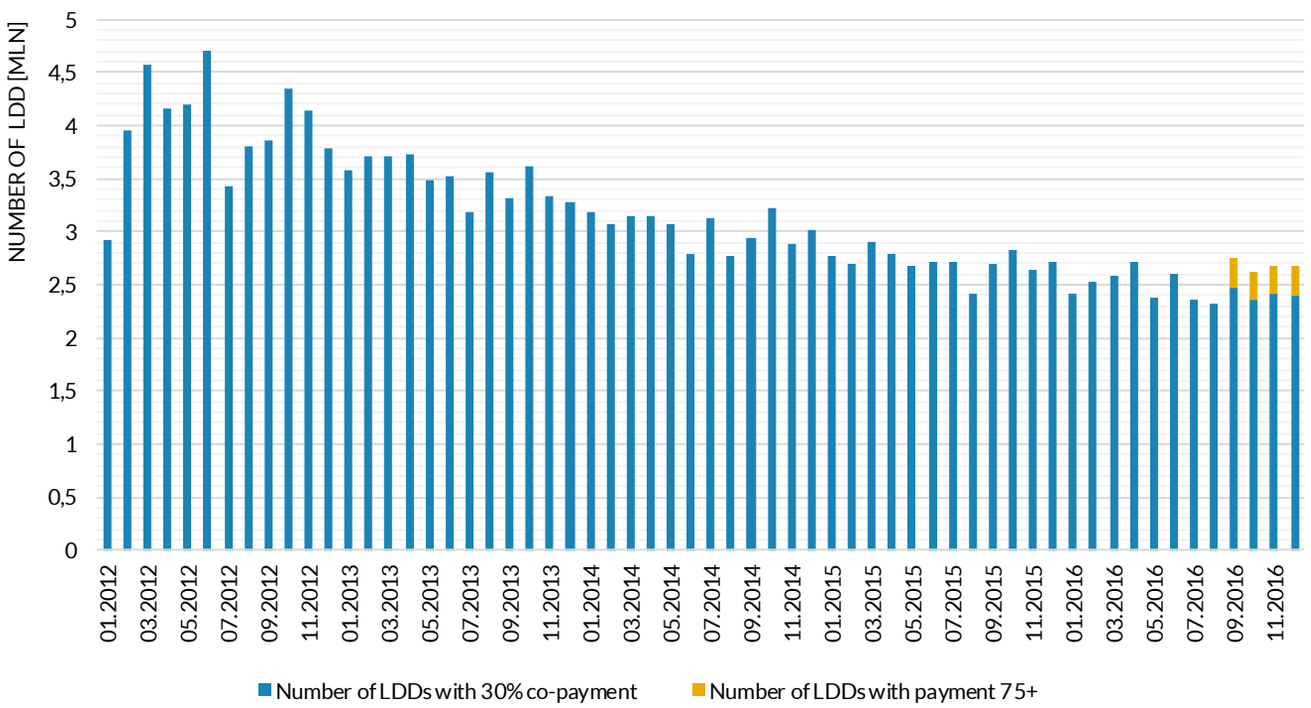
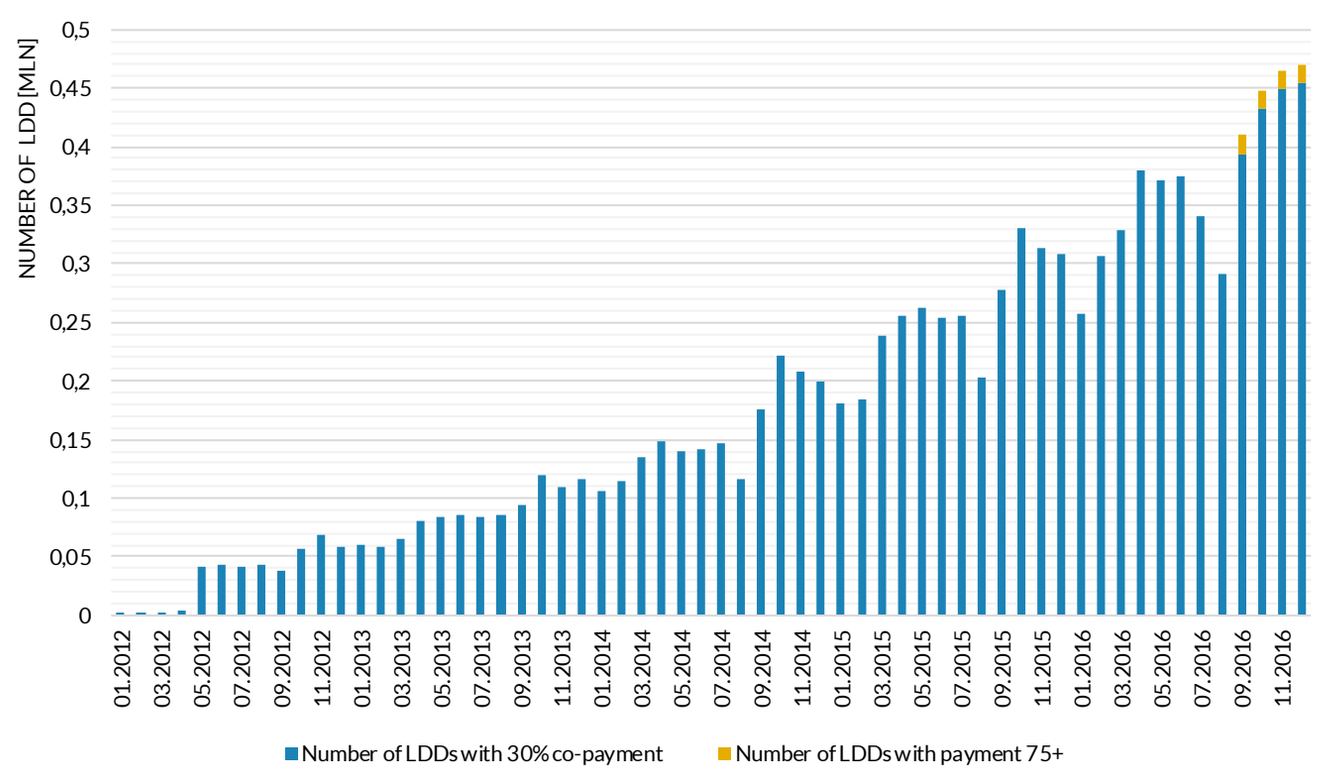


FIGURE 50.
LDD sales broken down by the type of payment for the limit group 231.0.



5.5.2. MEDICINES FOR SENIORS IN THE TREATMENT OF GLAUCOMA

Glaucoma is a group of chronic and progressive eye diseases, in which the visual nerve is gradually damaged. As a consequence, glaucoma reduces field of vision and visual acuity. According to WHO, glaucoma is the second most common cause of blindness in developed countries after cataract. The disease is very dangerous as it leads to irreversible optic nerve damage and in consequence to blindness. The risk of developing glaucoma increases with age. The percentage of diagnosed glaucoma cases is between 0.5% before 50 years of age to 10% after 80 years of age. Forecasted number of people with glaucoma will increase in 2020 to almost 79,6 million of the world's population. Currently in Poland there are about 420 thousand people with diagnosed glaucoma, this number is expected to increase to over 600 thousand by 2035. The problem of glaucoma is its very low detection rate caused by the lack of clear symptoms, which is why about 70% cases are detected too late to save vision, even if intensive treatment is undertaken. The treatment of glaucoma lasts until the end of life, and the key issue of successful therapy is an early diagnosis and systematic administration of medication. [7]

Currently, glaucoma treatment is carried out with medicines from three limit groups:

- *211.0 Antiglaucoma drugs - parasympathomimetics - pilocarpine*,
- *213.0 Antiglaucoma drugs - beta-blocking agents administered in the eye*,
- *214.0 Antiglaucoma drugs - prostaglandin analogues administered in the eye - single-agent preparations and combined preparations*.

Now, there are 46 medicines on the list of medicines issued free of charge in the indication of glaucoma treatment. However, the latest available data on sales refer to December 2016, when 8 preparations from the above mentioned three limit groups were issued free of charge. From the limit group *214.0* only one preparation out of 39 available was refunded, so this group was omitted from the analysis, only group *211.0* comprising one preparation and a group *213.0* comprising 6 drugs were considered.

Only one preparation was issued free of charge in the limit group *211.0*. The payment for patients receiving a medicine that is in the limit group *211.0* (excluding 75+ payment) per 30 LDD amounted to PLN 3.16.

As can be seen from Figure 51, in September there was a noticeable increase in the amount of reimbursement in group *211.0*, in the following months the upward trend was maintained but significantly slowed down.

The number of LDDs sold followed a similar trend as the reimbursement level – in September there was a significant increase in LDDs sold, in the following months the upward trend was maintained, but its dynamics decreased significantly (Figure 52). However, the changes between IX–XII 2016 do not differ significantly from historical data and the share of reimbursement of payment 75+ is negligible. Hence, the introduction of payment for elderly people for this limit group had no significant impact on the reimbursement.

The second limit group in the analysed indication is group *213.0*. It is comprising 6 preparations, which were issued free of charge to senior citizens. Payments of patients not belonging to the 75+ group for these preparations as per 30 LDDs ranged from PLN 1.74 to PLN 11.19.

FIGURE 51.
Amount of reimbursement broken down by the type of payment, group 211.0.

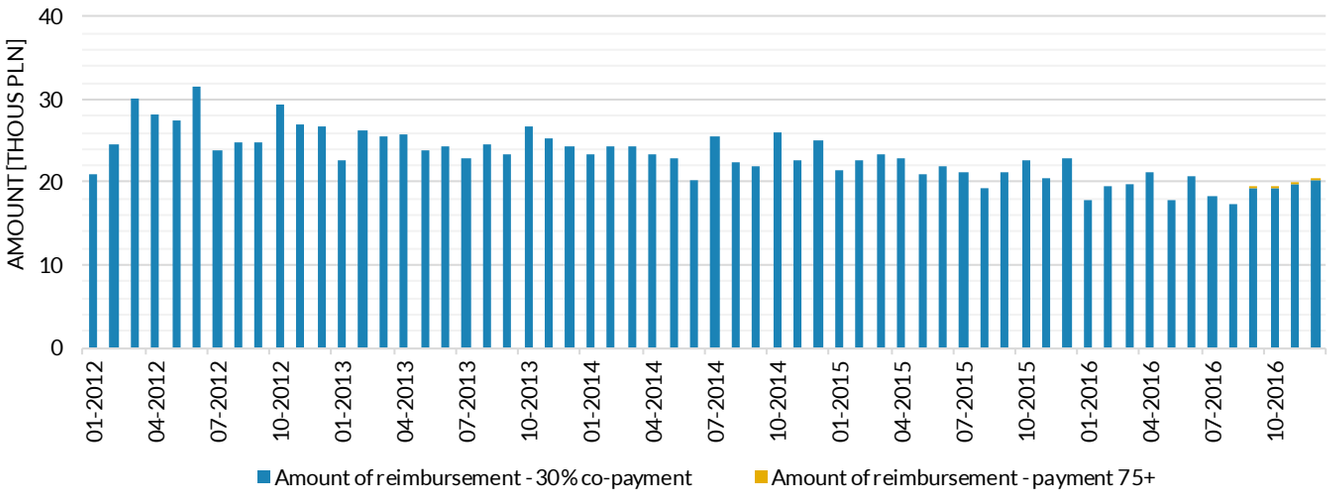
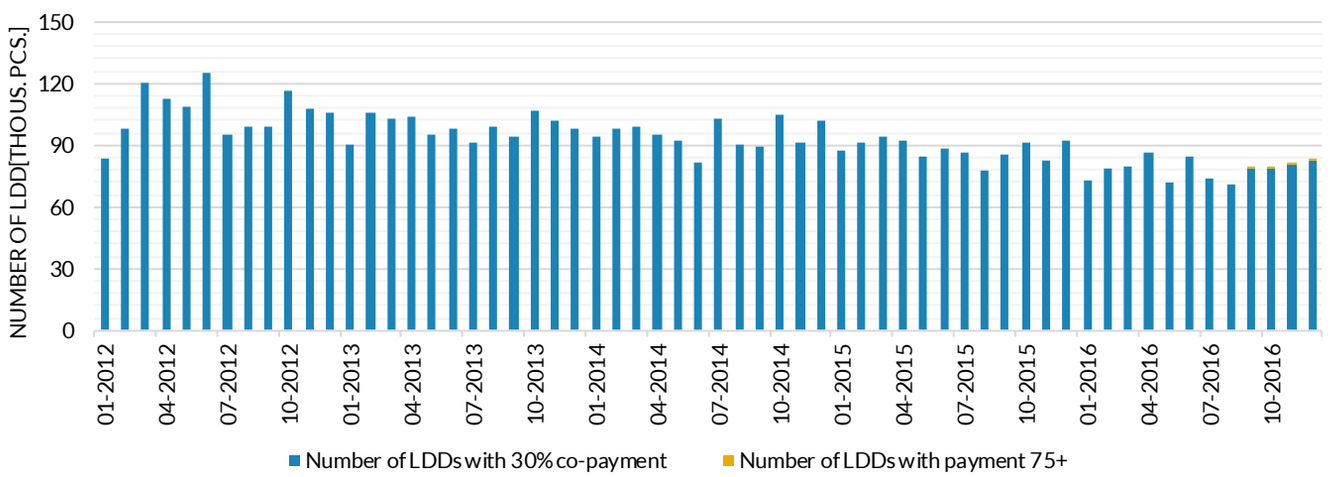


FIGURE 52.
Number of LDDs broken down by type of payment, group 211.0.



September saw a sharp increase in the amount of reimbursement compared to August, followed by a slight decrease in October and stabilisation in the next two months (Figure 53).

In group *213.0* similarly as in group *211.0* in September there was a significan t increase in sold LDDs, but it was not as pronounced in the following months. Due to the short observation period after the introduction of the list of medicines for seniors and seasonal increases and decreases in sales in the limit group, it is difficult to conclude whether the increase between September and December 2016 was caused only by the introduction of program 75+.

The share of seniors in the consumption of doses in analysed limit groups was negligible, it was decreasing month by month and varied from 2.15% in September to 0.87% in December (Table 22). The share of patients from 75+ group was so negligible that probably the decision to provide free medicines in these groups did not have any influence on the increase of sales, September increases in both the amount of reimbursement and the number of sold LDDs did not differ much from monthly fluctuations.

FIGURE 53.
Amount of reimbursement broken down by the type of payment, group 213.0.

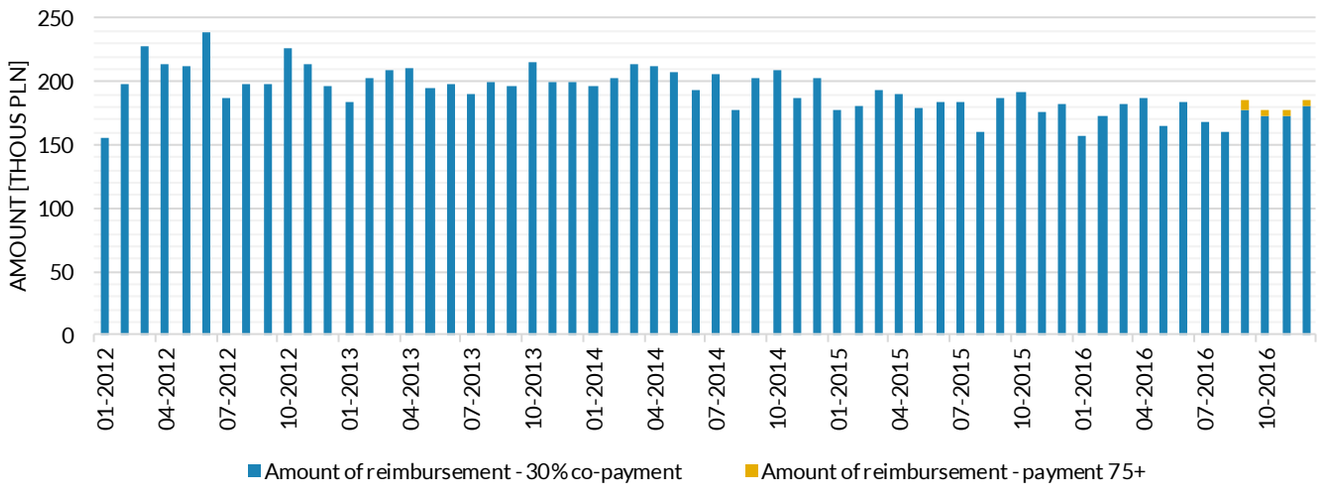


FIGURE 54.
Number of LDDs broken down by type of payment, group 213.0.

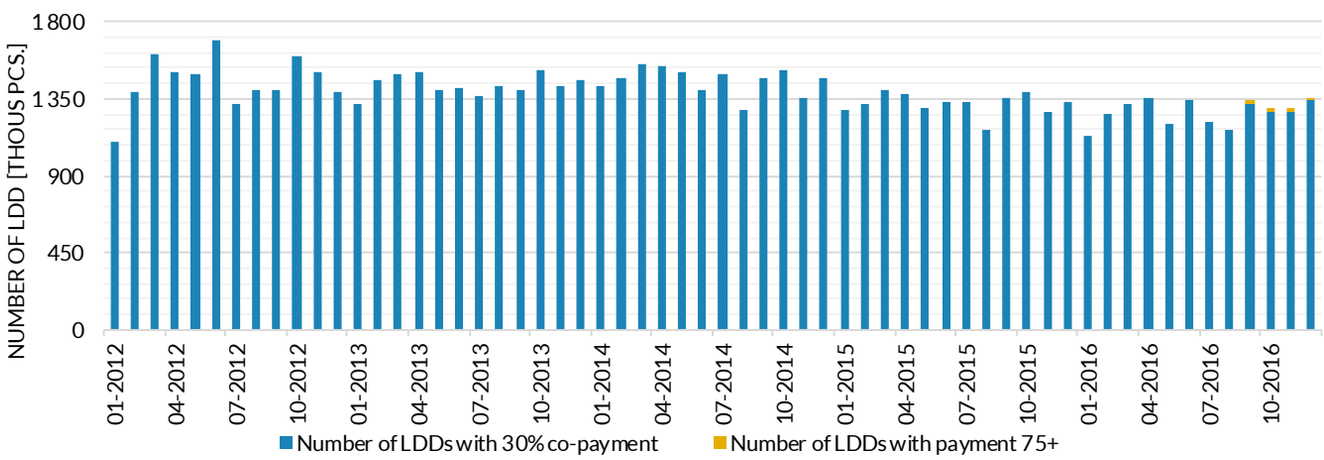


TABLE 22.
Share of reimbursed doses among seniors within the number of reimbursed doses in the entire population

ACTIVE SUBSTANCE	EAN CODE	09-2016	10-2016	11-2016	12-2016
Pilocarpinum	5909990237524	0.30%	0.86%	0.83%	1.45%
Betaxololum	5909990186518	1.85%	1.80%	1.92%	1.85%
Betaxololum	5909990186525	3.02%	2.69%	3.04%	3.57%
Betaxololum	5909990925513	0.57%	0.83%	0.63%	0.66%
Timololum	5909990187713	1.38%	0.68%	0.50%	0.15%
Timololum	5909990073719	1.81%	0.87%	0.78%	0.00%
Timololum	5909990073610	3.55%	1.18%	1.18%	0.00%
Total		**2.15%**	**1.40%**	**1.38%**	**0.87%**

5.6. Medicines at risk of unavailability on the territory of the Republic of Poland

In 2015, an amendment to the Pharmaceutical Law was adopted, primarily aimed at limiting the practice of outflow to other countries medicines, whose availability is threatened. There was introduced a control of the availability of medicines, drug export by wholesaler and the procurement of medicines. Data on inventory in warehouses, and transactions in pharmacies and hospital pharmacies are collected in the Integrated System for Monitoring Trading of Medicaments. Based on data from this system and other data on availability of medicines, the Minister of Health issues (in the form of an announcement) a list of medicines at risk of unavailability in Poland. A wholesaler wishing to export a medicine that is on this list will have to inform the Main Pharmaceutical Inspector of this fact. The authority will have 30 days of the objection period to oppose the export of this product. According to the amendment to the Law, pharmacies and wholesalers will order medicines in writing or electronically, which will make the control of wholesalers more effective regarding the actual inventory of medicines. [8]

In 2016, there were seven Minister of Health announcements on the list of medical products, foodstuffs intended for particular nutritional uses and medical devices threatened by lack of availability on the territory of the Republic of Poland.

Figure 55 presents the changes on subsequent lists of medicines at risk of unavailability in 2016, while Figure 56 presents lists narrowed down to reimbursed medicines.

FIGURE 55.
Number of EAN codes on subsequent lists of medicines threatened with unavailability, including changes in respect to the previous announcement

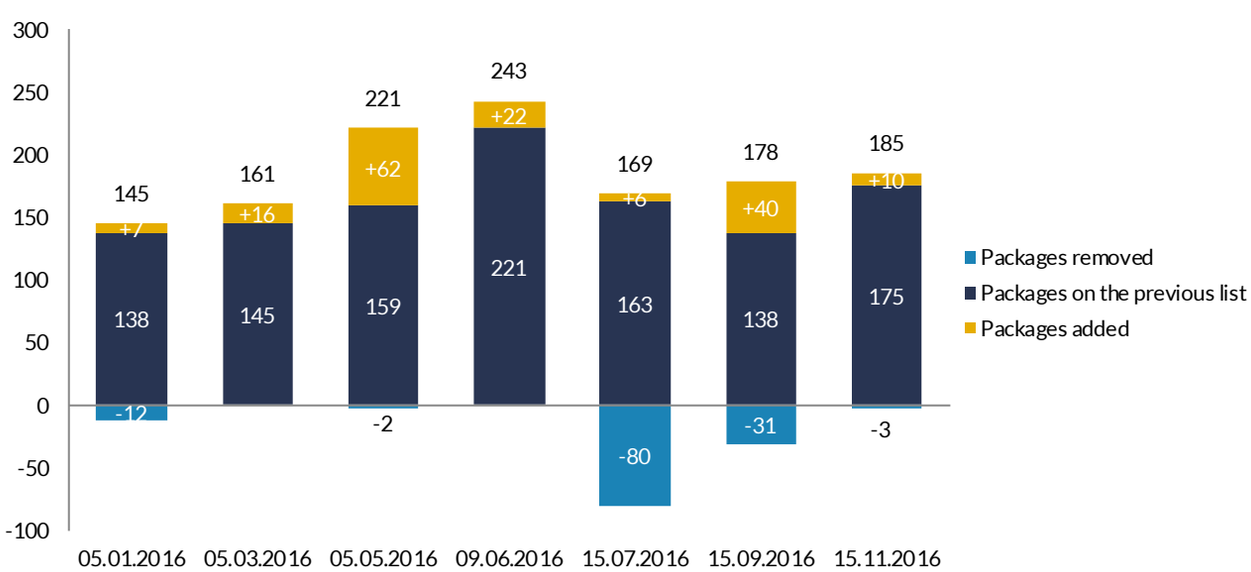
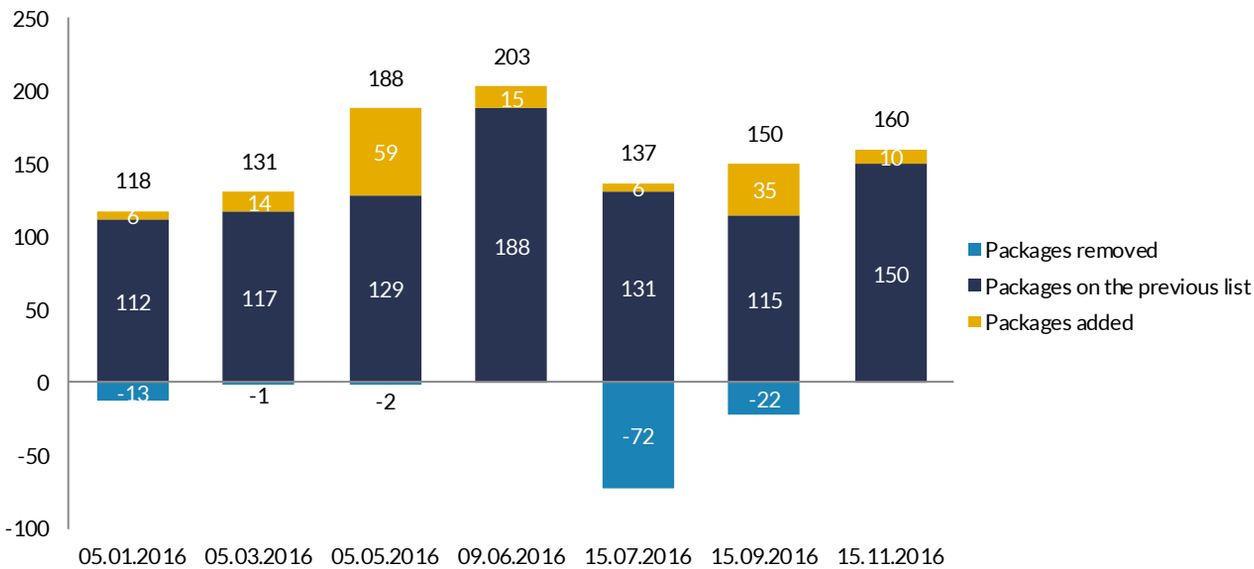


FIGURE 56.

Number of EAN codes on subsequent lists of medicines threatened with unavailability, including changes in respect to the previous announcement



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ikarpro.pl

INTERNET COMPENDIUM OF REIMBURSEMENT
ANALYSES WITH FORECASTING

It is an innovative service which combines:

- quick access to reimbursement databases
- broad range of analytical tools
- easy to be found important information

IKAR pro was built on experience gathered from years of work in the area of health technology assessment and reimbursement. Systematic analysis of reimbursement data facilitated the development of tools and solutions presented in a simple and standardised manner. Intuitive design of the platform supports time-effective information search.

Comprehensive build of the platform aims at supporting monitoring and analytical processes of medical devices market.

What does IKAR pro include?

IKAR pro was developed in agreement with the Act of Health Ministry of Poland from 12 May 2011 relating to reimbursement of medicines, foods for special medical purposes and medical devices. The platform contains current and historical information on reimbursed products.

Website is based mostly on the reimbursement data:

- from the announcements of the Minister of Health published since 1 January 2012,
- published by the NHF's departments on value and number of reimbursed packagings,
- on product recommendations collected from 8 major HTA agencies in Poland and the world (AOTM, CATDH, PBAC, PTAC, NHS Scotland, NCPE, NICE, HAS)

IKAR pro possesses also more advanced functionalities available for individual users upon logging–in.

Who is it addressed for?

IKAR pro is a platform allowing for quick access to up-to-date data on reimbursed drugs. The platform facilitates complex analyses on reimbursement data in Poland (We are working on extending the database to include information from other countries). IKAR pro is addressed to all stakeholders in the reimbursed pharmaceuticals market, in particular for:

- regulators and public payers
- public healthcare institutions
- medical and clinical experts
- marketing authorisation holders
- medical entities.

ASK ABOUT ACCESS

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