



## News, current issues

- **Legislations** come into force between 01/12/2016 and 01/01/2017: Act XI of 1991 (01.01.2017); Act LXXXIII of 1997 (01.01.2017); Act CLIV of 1997 (01.01.2017); Act XCV of 2005 (01.01.2017); Act XCIV of 2006 (01.01.2017); Act XCVIII of 2006 (01.01.2017); NM Decree No.9/1993. (01.01.2017); Gov.Decree No.43/1999. (01.01.2017); Gov.Decree No.112/2000. (01.01.2017); Gov.Decree No.337/2008. (01.01.2017); Gov.Decree No.235/2009. (01.01.2017); Gov.Decree No.180/2010. (01.01.2017); Gov.Decree No.323/2010. (03.12.2016,01.01.2017); Gov.Decree No.364/2010. (01.01.2017); Gov.Decree No.313/2011. (01.01.2017); Gov.Decree No.16/2012. (01.01.2017); Gov.Decree No.46/2012. (01.01.2017); ESzCsM Decree No.32/2004. (01.01.2017); EüM Decree No.5/2004. (01.01.2017); EüM Decree No.25/2006. (01.01.2017); EüM Decree No.14/2007. (01.01.2017); EüM Decree No.28/2010. (01.01.2017); EüM Decree No.31/2010. (01.01.2017); NEFMI Decree No.11/2011. (01.01.2017); NEFMI Decree No.12/2011. (01.01.2017)
- **NEWS [HUN]:** "About the transformation of NHIF" [link](#)
- **NEWS [EN]:** "Life-extending capacity of new cancer drugs" [link](#)
- **NEWS [HUN]:** "Possible future of healthcare" [link](#)
- **NEWS [HUN]:** "Figures indicate serious lack of GPs" [link](#)
- **NEWS [EN]:** "The most exciting medical technologies of 2017" [link](#)
- **NEWS [HUN]:** "Healthcare to be reformed" [link](#)
- **NEWS [HUN]:** "Finance of hospitals will be outsourced" [link](#)

## Macro approach to financing healthcare and medicinal products

### Balance of the Health Insurance Fund

Health Security Fund	2015. I-XII.	2016 original appropriation	2016		
			I-XI. months	% of appropriation	% of last year
<b>Total of Budgetary Expenditures</b>	<b>1 955,3</b>	<b>1 963,7</b>	<b>1 856,8</b>	<b>103,2%</b>	<b>105,5%</b>
Curative preventive provisions	960,6	982,4	911,4	101,2%	106,4%
Medicine subsidies	326,2	305,1	310,9	111,2%	106,2%
Medicine subsidies (pharmacy)	310,6	231,4	297,3	140,2%	105,2%
<b>Total of Budgetary Revenues</b>	<b>1 925,4</b>	<b>1 963,7</b>	<b>1 849,8</b>	<b>102,8%</b>	<b>105,3%</b>
Social Security Contributions	1 223,4	1 417,0	1 335,2	102,8%	120,0%
Contribution of Pharmaceutical Manufacturers and Wholesalers	65,3	58,0	65,5	123,2%	110,3%
<b>Balance</b>	<b>-29,9</b>	<b>0,0</b>	<b>-6,9</b>		<b>164,0%</b>

Billion HUF

In expenditures and revenues of 2016 budget, there is 2,77% increase compared to appropriation of 2015 and 0,43% increase compared to fulfilment of 2015. The central budget contribution is planned to be less with 26,5% than last year fulfilment, and this gap is filled with the 18,2% higher social security contribution (218 billion HUFs). The medicine subsidies plan is lower with 21,2 billion HUFs than last year expenses, but higher with 7 billion HUFs than the last year's original appropriation. In the first eleven months of 2016 the Health Security Fund produced a 0,39% deficit. Medicine subsidies shows 11,2% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission (+12,5 billion HUFs; +169%), and reimbursement of medicines without reference price group.

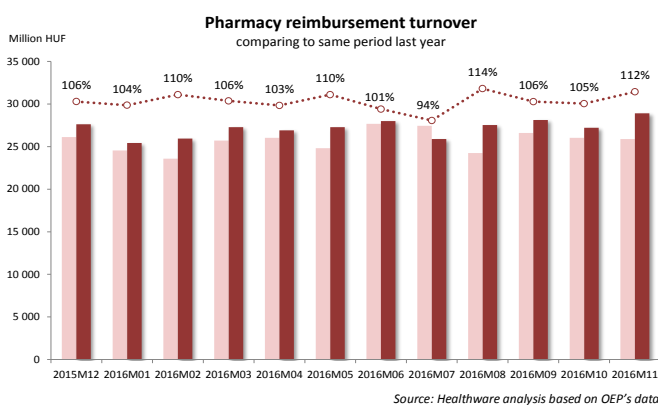
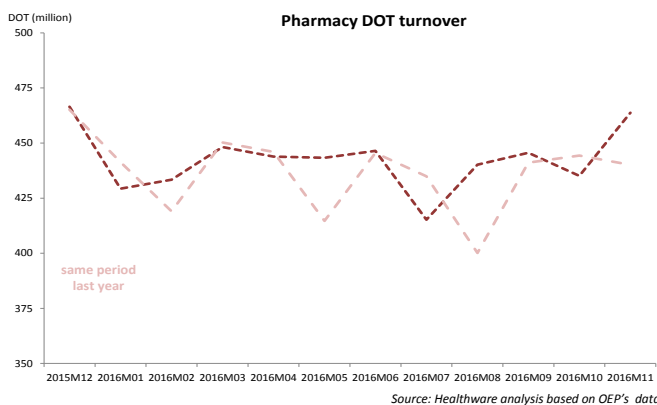
## Changes to subsidised medicinal product categories

Changes in the public drug list	2016 Aug.	2016 Sep.	2016 Oct.	2016 Nov.	2016 Dec.	2017 Jan.	2017
Number of new products	15	47	31	32	12	25	25
Number of new AI	0	0	3	15	0	6	6
Number of delisted products	31	6	10	28	33	21	21
<b>Prices</b>							
Decrease	2	3	98	11	5	11	11
Increase	0	0	1	1	0	3	3

Changes in the public drug list	2016 Aug.	2016 Sep.	2016 Oct.	2016 Nov.	2016 Dec.	2017 Jan.	2017
<b>Reimbursement</b>							
Decrease	0	5	237	5	4	27	27
Increase	36	0	28	5	0	6	6
<b>Co-payment</b>							
Decrease	2	7	150	19	5	20	20
Increase	36	1	152	1	0	17	17

Source: Healthware analysis based on OEP-PUPHA data

## Dynamics of the sales/circulation of prescription-only-medicine



Prescription drugs' DOT turnover in 2015 was 1,04% higher than in 2014, so the trend of drug consumption is still increasing, but in slower rate than in 2014 (2.74%) or 2013 (2.23%); while the reimbursement turnover was higher with 7.44%. The average reimbursement per DOT was higher with 6,34% than the 2014's average. New innovative reimbursement decisions were made in 2014 and 2015 generated 3,1% and 0,65% of annual reimbursement turnover, while only 0,4% of annual DOT turnover. Drug sales in the first eleven months of 2016 was 1.40% higher than the same period last year, while the average reimbursement per DOT increased with 4.18%. The reimbursement turnover was higher with 5.64% for this period compared to last year.

## Burden of disease analysis

The indirect costs of therapies can currently be validated in only a limited way in health economic analysis made from local financing viewpoint. However, in other levels of decision making the cost analyses, which are made in social approach, can include objective and well communicable messages. These details can aid in forming of preferences between different healthcare technologies. By way of data-request from OEP we provide the summing up of the following information:

- Demographic and epidemiologic characteristics (by age, sex and comorbidity)
- Dispersion of patients by disease severity based on pharm. treatment pattern
- Cost analyses (on data of prescr., inpatient and outpatient care, labs and diagnostic services, hospice, sickness benefit)

We suggest the patient survey method to define the patients indirect costs and the other state expenditure

- Sickness absence costs
- Home remodeling costs
- Informal care
- Other indirect burdens

More information about our services: [link](#)

Product offering



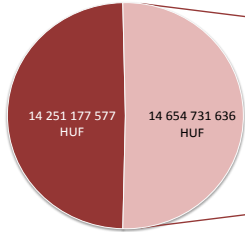
## Market data

### Marketing authorisation information

2015	EMA	OGYI	2016 - Q3	EMA	OGYI	November 2016	EMA	OGYI
New brands	91	190	New brands	19	39	New brands	6	14
New SKUs	1 081	2 254	New SKUs	107	309	New SKUs	79	84

Source: Healthware analysis based on OGYI's and EMA's data

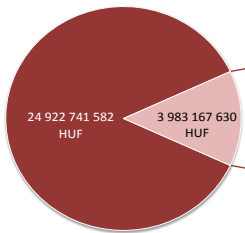
### TOP10 DISTRIBUTOR by all reimbursement paid in November 2016



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 873 479 456 HUF
SANOFI-AVENTIS Zrt.	1 924 319 515 HUF
TEVA Gyógyszergyár Zrt.	1 474 432 686 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	1 469 989 280 HUF
EGIS Gyógyszergyár Zrt.	1 457 926 109 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 352 873 703 HUF
Pfizer Kft.	1 216 227 064 HUF
Novo Nordisk Hungária Kft.	1 091 334 251 HUF
Sandoz Hungária Kereskedelmi Kft.	964 946 429 HUF
Lilly Hungaria Kft.	829 203 142 HUF

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

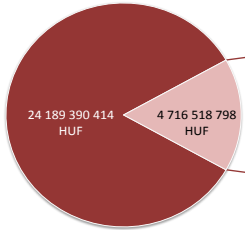
### TOP10 BRAND by all reimbursement paid in November 2016



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	646 186 977 HUF
GLIVEC	Novartis Hungária Kft.	534 206 466 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	493 086 067 HUF
IMBRUVICA	Janssen-Cilag Gyógyszerkereskedelmi Market	484 597 679 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m.	315 440 278 HUF
TASIGNA	Novartis Hungária Kft.	315 057 928 HUF
TECFIDERA	Biogen Hungary Korlátolt Felelősségű Társaság	311 681 564 HUF
SUTENT	Pfizer Kft.	297 493 158 HUF
XARELTO	Bayer Hungária Kereskedelmi és Szolgáltató Kft.	294 640 556 HUF
HUMULIN	Lilly Hungaria Kft.	290 776 957 HUF

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

### TOP10 ATC by all reimbursement paid in November 2016



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	646 186 977 HUF
V06D	other nutrients	612 127 446 HUF
N05AX13	paliperidone	563 123 809 HUF
L01XE01	imatinib	534 206 466 HUF
L01XE27	ibrutinib	484 597 679 HUF
C10AA07	rosuvastatin	449 741 813 HUF
A10AE04	insulin glargine	437 551 263 HUF
A10AB01	insulin (human)	346 207 451 HUF
C09BA04	perindopril and diuretics	327 335 615 HUF
R03BB04	tiotropium bromide	315 440 278 HUF

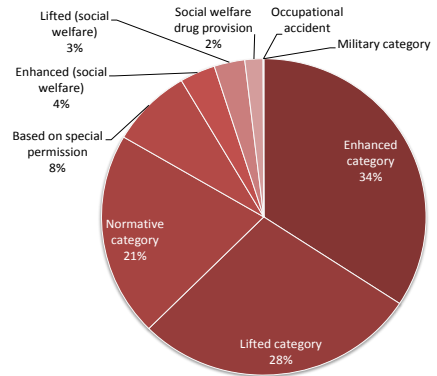
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

### Average number of medical sales reps; 11/2016

All	1 897
Medical products	1 596
Medical aids	265
Both	35

Source: Healthware analysis based on OGYI's

### Drug reimbursement by legal title; 11/2016



Source: Healthware analysis based on the sales

### TOP10 ATC by number of patients in November 2016

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	360 456
C09BA04	perindopril and diuretics	303 376
C08CA01	amlodipine	260 753
C07AB12	nebivolol	259 250
A02BC02	pantoprazole	238 960
C10AA07	rosuvastatin	230 706
A11CC05	coleciferol	224 343
M04AA01	allopurinol	221 788
C10AA05	atorvastatin	219 985
C09AA04	perindopril	185 120

Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

## Analysys of published list of reimbursement submissions in 2016 — Case study

Present case study reports the analysis of the published list of reimbursement dossiers (of medicines and nutrients) received by the National Health Insurance Fund of Hungary (NHIF). Subjects of the analysis were dossiers that were submitted to NHIF in 2016 only.

In the year 2016, considering different drug formulations and dosages as one item, listing the brands, the National Health Insurance Fund received totally 177 submissions. Stratified for indication areas the number of these was 196. It is not considered as a relevant change compared to year 2015 (180 and 208 submissions, respectively). The number of submissions with an evaluation period of 90 and 60 days were 83 (42%) and 113 (58%). Similar rates (38% and 62%) were observed in 2015. From these 121 are reimbursed (90-day submissions: 26; 60-day submissions: 95), five were refused (90-day submission: 2; 60-day submissions: 3), and 63 were not yet appraised by the Insurance Fund at the time of the analysis (90-day submissions: 52; 60-day submissions: 11). Number of reimbursed submissions were decreasing compared to 2015 (141 submissions). In addition rate of submissions with a 90 day evaluation period were not decreasing significantly (27), compared to rate of submissions with a 60 day evaluation period (116).

In case of the submissions with a 90 day evaluation period, the submissions included anti-cancer drugs in most cases, as in the previous year. The average time from request to decision was 153 days in case of closed submissions (31). This is a significant change compared to the previous year when the average time was 117 days. Additionally this data is significantly more than 90 days. Ongoing procedures (52) were not considered when this average value was determined. Looking at the temporal distributions, most of the submissions arrived to the Payer in April and December (22-12), in other months of the year the average number of submission were 5.5. In case of the submissions with a 90 day evaluation period the most common reimbursed products were long-acting insulins and monoclonal antibodies/protein kinase inhibitors in 2015 and 2016, respectively.

The same inclusion criteria were applicable to the submissions with a 60 day evaluation period. The following preparations were the most commonly evaluated by the Insurance Fund: nutritional, psycholeptics, psychoanalptics, anti-cancer drugs and drugs for Parkinson's disease. The average time from request to decision was 36 days in case of closed submissions (102). This period is similar to the average time in the previous year. It is also noticeable that numerous submissions with a 60 day evaluation period have been completed before deadline. Ongoing procedures (11) were not considered when this average value was determined. Looking at the temporal distributions, most of the submissions arrived to the Payer in July and August (16-16), in other months of the year the average number of submission were 9.8. Matrix for 60-day submissions represents ATC7 with the most occurrences, type of reimbursement and decision, which shows the more dynamic markets regarding the generic products, and also includes those submissions where the patent may expire in months after the decision.

### Methodology

Prior to analysis the following rules were defined: in case there were two or more submissions with the same brand name for the same indication but with different dosage and/or different packaging they were counted as a single submission. In case a single brand or a brand with different dosages and/or packaging had multiple indications it counted as multiple submissions. Furthermore two types of reimbursement requests were distinguish based on the length of the assessment process (90 or 60 days). In the results below fourth level ATC codes were sorted in a descending order based on the number of their occurrence in 2016 within the subgroup of 90-day submissions while fifth level ATC codes were used to find substances with the highest incidence regarding the number of HTA submissions in 2016 within the subgroup of 60-day submissions.

The following tables show the number of submissions with 90 day and 60 day evaluation periods grouped according to reimbursement categories.

Type of submission	ATC	INN	Normative 0 "Normatív 0"		Lifted "Emelt"		Enhanced "Kiemelt"		Itemized accounting "Tételes"		Special budget "Különkeret"		Sum	
			Reimbursed	Not yet appraised	Reimbursed	Not yet appraised	Reimbursed	Not yet appraised	Reimbursed	Not yet appraised	Reimbursed	Not yet appraised	Reimbursed	Not yet appraised
90 days	L01XC	monoclonal antibodies												
90 days	L01XE	protein kinase inhibitors					2	3	7				3	9
90 days	B02BD	blood coagulation factors					1	3	5				3	6
90 days	L04AC	interferon inhibitors								4	1	1	3	1
90 days	J05AR	antivirals for treatment of HIV infections, combinations					3						3	3
90 days	L04AA	selective immunosuppressants					1	1	1				2	1
90 days	L03AX	other immunostimulants						2					2	2
90 days	C09DX	angiotensin II antagonists, other combinations			2								2	2
90 days	L01XX	other antineoplastic agents						1	1				1	1
90 days	B01AF	direct factor Xa inhibitors			1	1							1	1
60 days	N06AX21	duloxetine	2			12								14
60 days	V06D	nutrients		3	2	3	1	2	1	1				7
60 days	N05AX12	antipsychotics												6
60 days	L03XE01	imatinib						6						6
60 days	N04BD02	rasagiline					5							5
60 days	C01EB17	ivabradine	1			3	1							4
60 days	L01BA04	penicillins							4					4
60 days	N03AX16	pregabalin		1										2
60 days	J02AC01	flucanazole		1		1	1	1						2
60 days	C09DB01	valsartan and amlodipine			2									2