

News, current issues

- **Legislations** come into force between 01/01/2017 and 01/02/2017: Act XI of 1991 (01.01.2017); Act LXXXIII of 1997 (01.01.2017,01.02.2017); Act CLV of 1997 (01.01.2017); Act XCV of 2005 (01.01.2017); Act XCVII of 2006 (01.01.2017); Act XCVIII of 2006 (01.01.2017,19.01.2017); NM Decree No.9/1993. (01.01.2017); Gov.Decree No.284/1997. (15.01.2017); 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. (01.01.2017,02.01.2017); Gov.Decree No.323/2010. (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.1/2003. (01.01.2017); ESzCsM Decree No.32/2004. (01.01.2017); EüM Decree No.4/2000. (01.01.2017); EüM Decree No.5/2004. (01.01.2017); EüM Decree No.43/2005. (01.01.2017); EüM Decree No.52/2005. (01.01.2017); EüM Decree No.25/2006. (01.01.2017); EüM Decree No.14/2007. (01.01.2017); EüM Decree No.53/2007. (01.01.2017); EüM Decree No.13/2009. (01.01.2017); EüM Decree No.28/2010. (01.01.2017); EüM Decree No.31/2010. (01.01.2017)
- **NEWS [HU]:** "Healthcare revolution in Hungary?" [link](#)
- **NEWS [HU]:** "New cancer drug will be tested on humans" [link](#)
- **NEWS [HU]:** "Sad news about healthcare of Hungary" [link](#)
- **NEWS [HU]:** "10 most expensive diseases in Hungary" [link](#)
- **NEWS [HU]:** "E-prescription by the end of 2017" [link](#)
- **NEWS [EN]:** "Human medicines highlights 2016" [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-XII. months	% of appropriation	% of last year
Total of Budgetary Expenditures	1 955,3	1 963,7	2 133,1	108,6%	109,1%
Curative preventive provisions	960,6	982,4	1 089,9	110,9%	55,7%
Medicine subsidies	326,2	305,1	349,8	114,7%	36,4%
Medicine subsidies (pharmacy)	310,6	231,4	327,9	141,7%	100,5%
Total of Budgetary Revenues	1 925,4	1 963,7	2 043,9	104,1%	658,0%
Social Security Contributions	1 223,4	1 417,0	1 479,5	104,4%	76,8%
Contribution of Pharmaceutical Manufacturers and Wholesalers	65,3	58,0	71,6	123,4%	5,9%
Balance	-29,9	0,0	-89,2		-136,7%

Billion HUF

In 2016 the Health Security Fund's deficit was 89,2 billion HUFs, while the revenues exceeded the provision with 80 billion HUFs (+4,09%), the expenditures was higher with 169 billion HUFs (+8,63%). The contribution of pharmaceutical manufacturers and wholesalers was higher with 13,6 billion HUFs (+23,4%), due to the higher revenue (+10,8 billion HUFs / +154%) from price volume agreements (PVA) and other contributions (+2,8 billion HUFs / +5,43%). The fulfilment of medicine subsidies was higher with 44,7 billion HUF (+14,7%) than the original appropriation, of which special purchase medicine took 6.2 billion HUF (+39.5%). Pharmacy drug expenditures shows 96.5 billion HUF (41.7%) overspending, partly because the appropriation does not include repayments, that added 71.6 billion HUF to the appropriation in the last quarter. Pharmacy drug expenditures were fulfilled with 25 billion HUF (+10.8%) actual overspending, compared to the appropriation. The overspending occurred mainly for two reasons, the higher turnover of medicines via compassionate care (+14,2 billion HUFs / +175%) and higher reimbursement turnover of medicines without reference price group (+6%).

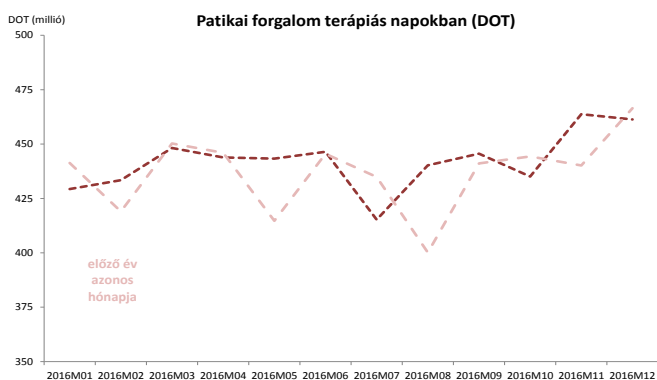
Changes to subsidised medicinal product categories

Changes in the public drug list	2016 Sep.	2016 Oct.	2016 Nov.	2016 Dec.	2017 Jan.	2017 Feb.	2017
Number of new products	47	31	32	12	25	13	38
Number of new AI	0	3	15	0	6	1	7
Number of delisted products	6	10	28	33	21	228	21
Prices							
Decrease	3	98	11	5	11	4	15
Increase	0	1	1	0	3	3	6

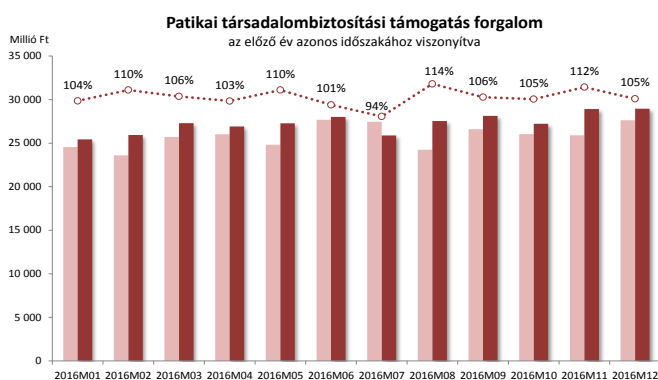
Changes in the public drug list	2016 Sep.	2016 Oct.	2016 Nov.	2016 Dec.	2017 Jan.	2017 Feb.	2017
Reimbursement							
Decrease	5	237	5	4	27	2	29
Increase	0	28	5	0	6	3	9
Co-payment							
Decrease	7	150	19	5	20	8	28
Increase	1	152	1	0	17	3	20

Source: Healthware analysis based on OEP-PUPHA data

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



Source: Healthware analysis based on OEP's data



Source: Healthware analysis based on OEP's data

Prescription drugs' DOT turnover in 2016 was 1.18% higher than in 2015, so the trend of drug consumption is still increasing, but in slower rate than in 2014 (2.74%) or 2013 (2.23%). Meanwhile, the reimbursement turnover was higher with 5.56%, because of the additional 14.2 billion HUF fulfillment of special permission appropriation, the 6% growth of reimbursement turnover of out-of-fix group products, and stagnation of fixed market. The average reimbursement per DOT was higher with 4.33% than the 2015's average. New ATCs that got authorized in 2014-2016 generated 7.6% of annual reimbursement turnover, while only 1.1% of annual DOT turnover.



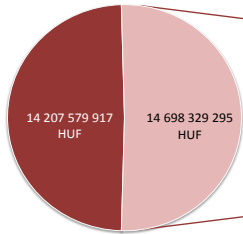
Market data

Marketing authorisation information

2016	EMA	OGYI	2016 - Q4	EMA	OGYI	dec.16	EMA	OGYI
New brands	70	167	New brands	9	39	New brands	2	13
New SKUs	622	1 669	New SKUs	120	376	New SKUs	30	79

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

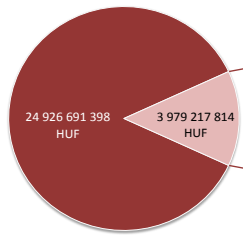
TOP10 DISTRIBUTOR by all reimbursement paid in December 2016



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 855 132 260 HUF
SANOFI-AVENTIS Zrt.	1 990 491 541 HUF
TEVA Gyógyszergyár Zrt.	1 486 891 896 HUF
EGIS Gyógyszergyár Zrt.	1 458 580 535 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	1 380 437 132 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 372 654 928 HUF
Pfizer Kft.	1 237 133 766 HUF
Novo Nordisk Hungária Kft.	1 112 427 390 HUF
Sandoz Hungária Kereskedelmi Kft.	970 232 497 HUF
Lilly Hungaria Kft.	834 347 349 HUF

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

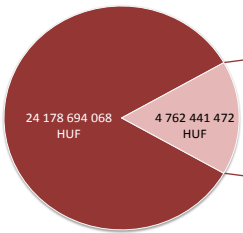
TOP10 BRAND by all reimbursement paid in December 2016



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	660 916 009 HUF
GLIVEC	Novartis Hungária Kft.	538 757 260 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	483 047 104 HUF
IMBRUVICA	Janssen-Cilag Gyógyszerkereskedelmi Market	434 877 408 HUF
TECFIDERA	Biogen Hungary Kórlátolt Felelősségs Társaság	337 856 368 HUF
TASIGNA	Novartis Hungária Kft.	312 346 352 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m.	307 888 274 HUF
XARELTO	Bayer Hungaria Kereskedelmi és Szolgáltató Kft.	306 901 089 HUF
SUTENT	Pfizer Kft.	301 792 612 HUF
HUMULIN	Lilly Hungaria Kft.	294 835 338 HUF

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

TOP10 ATC by all reimbursement paid in December 2016



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	660 916 009 HUF
V06D	egyéb tápszer	654 048 216 HUF
N05AX13	paliperidon	549 790 720 HUF
L01XE01	imatinib	539 576 972 HUF
A10AE04	insulin glargine	460 722 542 HUF
C10AA07	rosuvastatin	443 754 604 HUF
L01XE27	ibrutinib	434 877 408 HUF
A10AB01	insulin (human)	354 070 429 HUF
N07XX09	dimetil-fumarát	337 856 368 HUF
C09BA04	perindopril és vizelethajtók	326 828 203 HUF

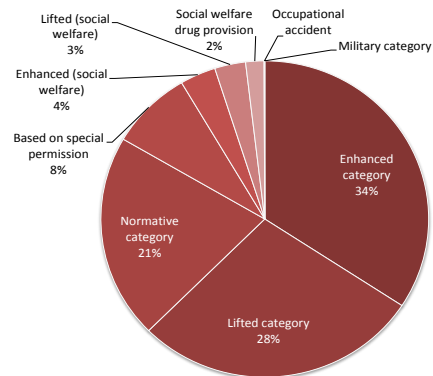
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Average number of medical sales reps; 12/2016

Medicinal products	1 266	Medical aids + nutritions	3
Medicinal products + aids	23	Nutritions	117
Medicinal products + nutritions	1	All	1 673
Medical aids	263		

Source: Healthware analysis based on OGYI's

Drug reimbursement by legal title; 12/2016



Source: Healthware analysis based on the sales

TOP10 ATC by number of patients in December 2016

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetilszalicilsav	355 469
C09BA04	perindopril and diuretics	302 740
C08CA01	amlodipin	259 571
C07AB12	nebulivol	256 787
A02BC02	pantoprazol	240 101
C10AA07	rosuvastatin	227 573
M04AA01	allopurinol	217 519
A11CC05	kolekalciferol	215 899
C10AA05	atorvastatin	215 802
C09AA04	perindopril	185 255

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

Enforceable allowances from payment obligations of pharm industry after R&D expenses — Case study

Based on the paragraphs (10)-(12) of the drug-economical Act¹, MAHs may require allowance from their repayment obligations, involving the 10% and 20% tax-payment obligation due to the ex-factory price-proportional reimbursement turnover of pharmacy drugs and Rep fees, depending on their R+D expenses. Measure of discount in current year might reach up to 20-60-90% of repayment obligations of previous year, depending on the rate of R+D expenses compared to ex-factory price-proportional reimbursement of previous year. Amount of R+D expenses to be taken into consideration are determined by Governmental Decree² including detailed rules and Acts about accounting³, corporate tax⁴ and innovation⁵. Current laws strictly limit considerable R+D investments, as well as entitled companies. Furthermore, in order to reach 90% discount, R+D investments need to reach more than 25% of ex-factory price-proportional reimbursement, and even in case of the lowest, 20% discount, the condition is to reach 15%. In all cases the minimum condition is to have personnel expenses in the rate of 3% of ex-factory price-proportional reimbursement. Based on the Governmental Decree No. 162/2009 (VIII. 3.), allowances can be enforced from the month of publishing annual report, but not earlier than July. Claimed allowance has no deadline, can be enforced as total amount, by fulfill the monthly payment obligations as net value (reduced with allowances). General condition of the claim is the continuous presence on the market of reimbursed pharmaceuticals, because the allowances can only decrease the expense of future repayment obligations. Measure of discount received on industry level is not publicly available, but the total amount might be estimated based on the 10% and 20% repayment obligations^{6,7}, number of sales representatives⁸, and the data published in discharges, and the fulfillments of Health Insurance Fund's payments⁹. Each calendar year, fulfillment takes place regarding repayment obligations of October – December of the year before, and January – September of recent year (according to legal regulations, fulfillment has to be done by the 20th day of 3rd month). For this period, 10% and 20% repayments and wholesale trade tax obligations can be calculated by using monthly level data, while Rep fees can be calculated based on data regarding first three quarters and whole year, published by the Health Fund. The payment obligations continue to significantly exceed the payments fulfilled, partly due to the deductions enforced by the repayments based on price-volume agreements which lower the 10% and 20% repayment obligation (yearly amount is also public information). Obligations to be fulfilled are significantly higher than fulfillment of title „Revenues and repayments from MAHs, distributors, wholesalers” even after the discount corrections due to price-volume agreements. As a result of the previously described, there's a yearly difference of 8.9-12.7 billion HUF between the sum defined as liability and the financially settled payments of the pharm industry between 2013 and 2016, which come from the upper limit of the deduction enforced at the industrial level on R&D expenses. According to the discharge acts the stocks of the back taxes are not significant, but the HUF 2-2.5 billion overpayment may include industrial payments that could not have been accounted for until the beginning of March due to the ongoing information flow between the National Tax and Customs Administration and the National Health Insurance Fund. Though, as a consequence these items could not be identified in the discharges, it stands to reason that these are a part of the current year's industrial payments, thus these may reduce the gap between the outstanding liabilities and the financially settled ones.

Table 1.: Differences between industrial payment obligations and fulfillment

	2013	2014	2015	2016
1. Payment obligations to be settled in the current year (arising from October, the year before to September, current year; estimation)	63 771 M	61 243 M	67 784 M	71 034 M
2. Enforced deductions from the 10-20% payment obligations due settled payments based on price volume agreements (NHIF) (-)	1 669 M	1 827 M	2 170 M	4 568 M
I. Adjusted payment obligations to be settled in the current year (1-2.)	62 102 M	59 416 M	65 614 M	66 467 M
II. Revenues and repayments from MAHs, distributors, wholesalers (fulfillment)	51 066 M	50 546 M	54 979 M	53 768 M
Difference between payment obligations and fulfillment (I-II)	11 036 M	8 870 M	10 635 M	12 699 M

There is no public information about the range of companies that are eligible for claiming this allowance. Only in the stock exchange reports¹⁰ continuously published by Richter can be found such data with which by comparing them to the public data above the claimed allowance of the manufacturer can be estimated. By comparing these to public data the deduction granted to the company may be estimated. In case of the 10% and 20% payment obligations only those products were taken into consideration, in which case the Richter was named as the distributor in the published payments data in the given month, whilst in case of the Rep fee payments the calculations were based on the average number of sales representatives in the lists published weekly by the National Institute of Pharmacy and Nutrition. Based on the reports between the business years of 2012 and 2016 Richter may have enforced the highest, 90% allowance based on the R&D expenditures of the year before, as a result the company reduced its payment obligations by HUF 2.8-3.5 billion.

Table 2.: Difference between accounted repayment obligations according to Richter Gedeon PIC. reports and arising obligations based on public information

Year	Arising payment obligations			Accounted obligations			Enforced deduction		
	10% és 20%	REP	Total	10% és 20%	REP	Total	10% és 20%	REP	Total
2012	1 900 M	1 841 M	3 741 M	487 M	431 M	918 M	1 413 M	1 410 M	2 823 M
2013	2 068 M	1 720 M	3 788 M	346 M	185 M	531 M	1 722 M	1 535 M	3 257 M
2014	2 059 M	1 677 M	3 736 M	168 M	162 M	330 M	1 891 M	1 515 M	3 406 M
2015	2 273 M	1 696 M	3 969 M	192 M	219 M	411 M	2 081 M	1 477 M	3 558 M
2016	2 416 M	1 680 M	4 095 M	369 M	253 M	622 M	2 047 M	1 427 M	3 473 M

EGIS, up to the business year of 2012/2013 – until stock exchange delisting – enforced 1.2 billion HUF allowance in 2012, and 2.3 billion HUF in the first three quarters of 2013 based on published reports¹¹. On 30th of September 2013, a further amount of HUF 3.4 billion was recorded as allowance to be deducted from the obligations, thus in 2013 and 2014 the payment obligations may have been reduced approximately by 3 billion HUF. 10% and 20% payment obligations and the number of registered sales representatives of EGIS had similar extent in the period of 2014-2016, so the enforced allowances are likely to have been similar as well, if the company was entitled to 90% allowance based on the R+D investments. Based on the strategic agreements¹² with the government member companies of the Teva, Servier, Sanofi-Aventis and GSK groups, or smaller manufacturers who are members¹³ of the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ), and who have also R+D activity, may be entitled to enforce allowances based on their R+D expenditures from their payment obligations.

