

News, current issues

- **Legislations** come into force between 01/09/2016 and 01/10/2016: Act LXXXIII of 1997 (01.09.2016); Act CLIV of 1997 (01.09.2016); Act XCV of 2005 (01.09.2016); Gov.Decree No.43/1999. (01.09.2016); Gov.Decree No.323/2010. (01.09.2016); NEFMI Decree No.12/2011. (30.09.2016)
- **NEWS [HU]:** "Tax payment obligation due to 2016 expenditure surplus is on the table" [link](#)
- **NEWS [EN]:** "Busting the billion-dollar myth: how to slash the cost of drug development" [link](#)
- **NEWS [HU]:** "Execution of the 2015 budget was submitted to Parliament" [link](#)
- **NEWS [EN]:** "UK plans 'fast track' for most cost-effective new medicines" [link](#)
- **NEWS [HU]:** "Innovative drugs in cancer treatment are inaccessible" [link](#)
- **NEWS [EN]:** "Study shows health improving globally, but progress is patchy" [link](#)

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Billion HUF

Health Security Fund	2015. I-XII.	2016 original appropriation	2016		
			I-VIII. months	% of appropriation	% of last year
Total of Budgetary Expenditures	1 955,3	1 963,7	1 342,1	102,5%	104,5%
Curative preventive provisions	960,6	982,4	658,4	100,5%	104,8%
Medicine subsidies	326,2	305,1	223,3	109,8%	104,7%
Medicine subsidies (pharmacy)	310,6	231,4	213,3	138,3%	103,7%
Total of Budgetary Revenues	1 925,4	1 963,7	1 351,2	103,2%	104,9%
Social Security Contributions	1 223,4	1 417,0	976,2	103,3%	119,9%
Contribution of Pharmaceutical Manufacturers and Wholesalers	65,3	58,0	48,1	124,4%	109,4%
Balance	-29,9	0,0	9,1		296,0%

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 eight months of 2016 the Health Security Fund produced a 0,7% surplus due to the higher social security contributions (+31,5 billion HUFs; +3,3%) and the lower expenditures of curative preventive provisions (-9,28 billion HUFs; -1,4%). Medicine subsidies shows 9,8% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission, and reimbursement of medicines without reference price group.

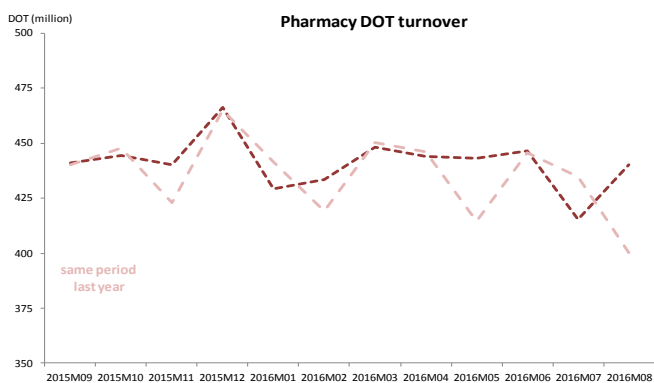
Changes to subsidised medicinal product categories

Changes in the public drug list	2016 May	2016 June	2016 July	2016 Aug.	2016 Sep.	2016 Oct.	2016
Number of new products	7	17	9	15	47	31	194
Number of new AI	0	0	2	0	0	3	11
Number of delisted products	19	1	11	31	6	10	168
Prices							
Decrease	1	0	43	2	3	98	245
Increase	0	0	5	0	0	1	9

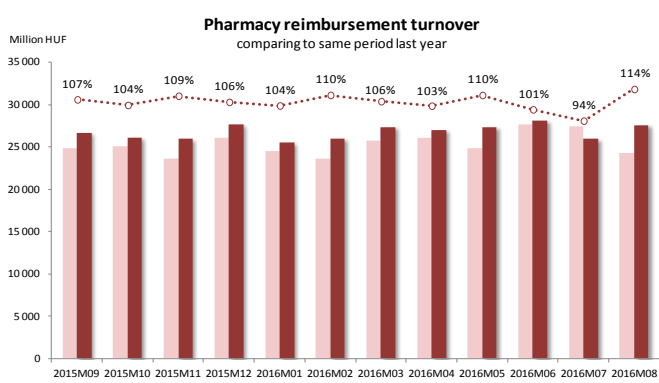
Changes in the public drug list	2016 May	2016 June	2016 July	2016 Aug.	2016 Sep.	2016 Oct.	2016
Reimbursement							
Decrease	1	0	53	0	5	237	498
Increase	0	0	6	36	0	28	234
Co-payment							
Decrease	2	0	52	2	7	150	490
Increase	0	0	23	36	1	152	352

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 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 seven months of 2016 was 1,4% higher than the same period last year, while the average reimbursement per DOT increased with 3,56%. The reimbursement turnover was higher with 5,01% for this period compared to last year.



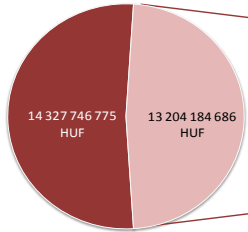
Market data

Marketing authorisation information

2015	EMA	OGYI	2016 - Q2	EMA	OGYI	August 2016	EMA	OGYI
New brands	91	190	New brands	20	57	New brands	5	10
New SKUs	1 081	2 233	New SKUs	161	542	New SKUs	19	139

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

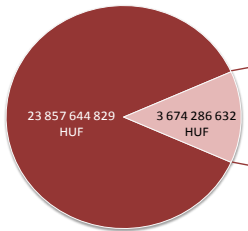
TOP10 DISTRIBUTOR by all reimbursement paid in August 2016



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 670 540 507 HUF
SANOFI-AVENTIS Zrt.	1 842 303 384 HUF
EGIS Gyógyszergyár Zrt.	1 415 912 867 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 301 706 882 HUF
Pfizer Kft.	1 162 210 372 HUF
TEVA Gyógyszergyár Zrt.	1 093 151 946 HUF
Novo Nordisk Hungária Kft.	1 059 275 998 HUF
Sandoz Hungária Kereskedelmi Kft.	919 187 241 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	888 392 139 HUF
Lilly Hungaria Kft.	851 503 350 HUF

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

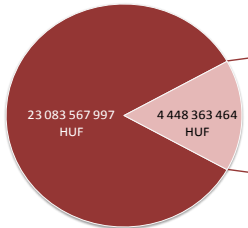
TOP10 BRAND by all reimbursement paid in August 2016



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	612 504 192 HUF
GLIVEC	Novartis Hungária Kft.	528 365 188 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	485 419 085 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m.	320 878 841 HUF
TASIGNA	Novartis Hungária Kft.	304 470 936 HUF
TECFIDERA	Biogen Hungary Korlátolt Felelősségű Társaság	303 865 113 HUF
HUMULIN	Lilly Hungaria Kft.	292 806 807 HUF
LANTUS	SANOFI-AVENTIS Zrt.	290 516 832 HUF
SUTENT	Pfizer Kft.	275 046 790 HUF
IMBRUVICA	JANSSEN-CILAG INTERNATIONAL NV	260 412 849 HUF

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

TOP10 ATC by all reimbursement paid in August 2016



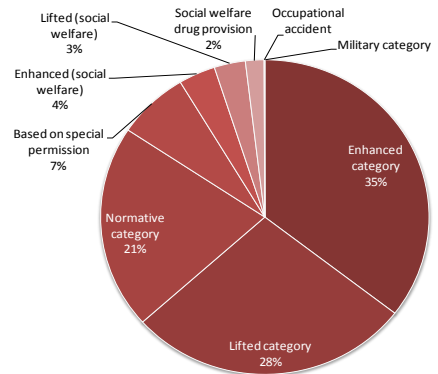
TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	612 504 192 HUF
V06D	other nutrients	611 581 155 HUF
N05AX13	paliperidone	554 347 775 HUF
L01XE01	imatinib	528 365 188 HUF
C10AA07	rosuvastatin	433 723 282 HUF
A10AE04	insulin glargine	409 633 602 HUF
A10AB01	insulin (human)	346 499 233 HUF
C09BA04	perindopril and diuretics	326 359 260 HUF
R03BB04	tiotropium bromide	320 878 841 HUF
L01XE08	nilotinib	304 470 936 HUF

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

Average number of medical sales reps; 08/2016

All	1 368
Medical products	1 114
Medical aids	239
Both	15

Drug reimbursement by legal title; 08/2016



Source: Healthware analysis based on the sales

TOP10 ATC by number of patients in August 2016

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	356 103
C09BA04	perindopril and diuretics	296 717
C08CA01	amlodipine	255 061
C07AB12	nebulivol	252 420
A02BC02	pantoprazole	225 888
C10AA07	rosuvastatin	223 224
C10AA05	atorvastatin	219 353
M04AA01	allopurinol	214 371
C09AA04	perindopril	179 572
C07AB07	bisoprolol	176 281

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

Transparency Report of Innovative Pharmaceutical Manufacturers — Case study

Member companies of the Association of Innovative Pharmaceutical Manufacturers published the transfers of value to healthcare professionals and organizations at the first time in 2016.

Reports were published on the webpages of the companies, based on the „[Transparency code on the disclosure of transfers of value to healthcare professionals and healthcare organisations](#)“. Although the disclosure has its limitations¹ regarding the pharmaceutical market, it still can provide useful information about that, how much companies spend on values in healthcare sector, while also their integration in the supply system as well as the extent and concentration of a secondary healthcare financing source can be analyzed.

Expenditures in sum

Transparency code precisely describes the categories in which manufacturers have to disclose the paid values, basically three types of them: individual named disclosures, other expenses unnamed due to legal barriers, and research and R&D transfers of value. Within the first two categories values paid to healthcare professionals, providers and organizations were separated and involved into further sub-categories (donations and grants, contribution to costs related to events, registration fees, travel and accommodation, additional costs) to be published.

Healthware collected the public information and organized in database, the results extracted are represented in the chart below.

	Named benefits	Unnamed benefits	Expenditures on R&D	Summary
Amount (HUF)	2 782 436 224	3 206 946 566	10 518 946 974	16 480 696 332
Reimbursement to companies in percentage	1,57%	1,81%	5,94%	9,30%
Producers price traffic of companies in percentage	1,63%	1,88%	6,17%	9,66%
Complete reimbursement in percentage	0,90%	1,03%	3,39%	5,31%
Complete producers price traffic in percentage	0,83%	0,96%	3,13%	4,91%

AIPM member companies who published these data transferred approximately 16.5 billion HUF as values, of which more than 60% was allocated for research and development expenses (which is not equal to R+D expenses with tax relief entitlement, but

allowances received by Healthcare professionals or Healthcare providers/organizations for clinical trials).

Transparency Reports and network research

Processing and summarizing transparency reports published by the companies, in case of the named values, also provides opportunity for analyzing health sector relations to the pharma industry, with the methods of network research.

In our example we processed the relations among pharmaceutical companies and hospitals. We organized the healthcare institutions involved in each transparency reports into a database and categories (hospital, individual entrepreneur, foundation, professional organization). We added the departments belong to the same hospital together, and indicated all the institutions with an individual identification.

Processing transparency reports might help to highlight the not-so-explored relations among healthcare institutions and pharmaceutical manufacturers: how much each companies spend on such purposes, how much they spend in the rate of reimbursement, and in case of named values there is an opportunity to examine which or who are the especially supported institutions, healthcare professionals, fields of health specializations. With the help of network research we can visualize in a new way the structure of this secondary form of financing, and later the yearly pattern change also can be analyzed.

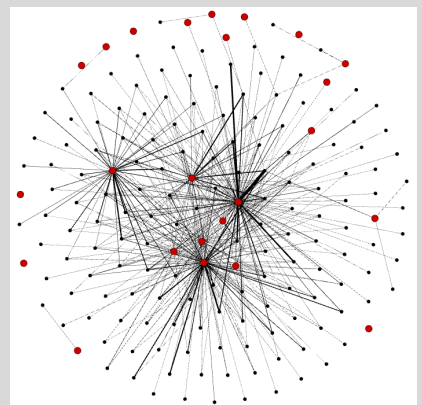


Figure 1. - Relationship network of drug manufacturers

The red nodes are the pharmaceutical companies, the black ones are the hospitals. The thickness of the lines is proportional to the financial benefits, the highest spending firms gravitate into the central of the network.

¹ The disclosure reports doesn't contain the benefits connected to the OTC drugs and allowances according to point 10.1 and 15 of the [Code of Ethics For Pharmaceutical Marketing Communications](#)