Special edition

Newsletter

Actualities of Hungarian pharmaceutical financing market

No.2, Issue IV. February 2016
Published: 23 February 2016

HEALTHWARE CONSULTING LTD.

News, current issues

- **Legislations** come into force between 01/01/2016 and 01/02/2016**:** Act XI of 1991 (01.01.2016,23.01.2016); Act LXXXIII of 1997 (01.01.2016); Act CLIV of 1997 (01.01.2016); Act II of 2000 (01.01.2016); Act XCV of 2005 (01.01.2016,23.01.2016); Act XCVII of 2006 (01.01.2016); Act XCVIII of 2006 (01.01.2016,23.01.2016); NM Decree No.9/1993. (01.01.2016); Gov.Decree No.284/1997. (01.01.2016); Gov.Decree No.43/1999. (01.01.2016); Gov.Decree No.337/2008. (10.01.2016); Gov.Decree No.235/2009. (01.01.2016); Gov.Decree No.180/2010. (10.01.2016); Gov.Decree No.319/2010. (01.01.2016); Gov.Decree No.323/2010. (01.01.2016); Gov.Decree No.313/2011. (01.01.2016); EüM Decree No.31/2010. (01.01.2016)
- **NEWS:** *"Which countries get the best - and worst - value healthcare?"* link
- **NEWS:** *"Few advantages of Hungarian healthcare system"* link
- **NEWS:** *"Seven $1 billion-plus drugs seen reaching market in 2016"* link
- **NEWS:** *"EU Regulation on the unique box IDs is published"* link
- **NEWS:** *"Seventy million patient-doctor meeting annually"* link
- **NEWS:** *"Profit is doubled by Richter"* link
- **NEWS:** *"Side effect researches for European companies too"* link
- **NEWS:** *"The remaining heritage of Kalmopyrin"* link

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Billion HUF

Health Security Fund	2014. I-XII.	2015 original appropriation	2015 I-XII. months	2015 % of appropriation	2015 % of last year
Total of Budgetary Expenditures	**1 907,1**	**1 910,8**	**1 955,3**	**102,3%**	**102,5%**
Curative preventive provisions	945,6	948,6	960,6	101,3%	101,6%
Medicine subsidies	302,3	298,1	326,2	109,4%	107,9%
Medicine subsidies (pharmacy)	286,4	224,4	310,6	138,4%	108,5%
Total of Budgetary Revenues	**1 907,1**	**1 910,8**	**1 925,4**	**100,8%**	**101,0%**
Social Security Contributions	896,3	1 198,5	1 223,4	102,1%	136,5%
Contribution of Pharmaceutical Manufacturers and Wholesalers	57,4	58,0	65,3	112,5%	113,8%
Balance	**0,0**	**0,0**	**-29,9**		**0,0%**

In 2015 the Health Security Fund's deficit was 29,9 billion HUFs, while the revenues exceeded the provision with 14,6 billion HUFs, the expenditures was higher with 44,5 billion HUFs. The contribution of pharmaceutical manufacturers and wholesalers was higher with 7,3 billion HUFs (+12,5%), due to the higher revenue (+3,3 billion HUFs / +46,8%) from price volume aggrements (PVA) and other contributions (+4 billion HUFs / +7,8%). The fulfillment of medicine subsidies was higher with 28,1 billion HUFs (+12,5%) than the original appropriation, and exceeded even the increased appropriation with 3,6 billion HUFs. The overspending occurred mainly the higher turnover of medicines via compassionate care (+12,8 billion HUFs / +232%).

Public turnover data in our Medalyse service

With our service Medalyse for our clients, public turnover data published by NHIF is easily available and it is possible to follow them with time series analysis.

The turnover data – considering the experience of past half year – is published after a shorter period by NHIF, so it is available on the following 16-18th day after the given month.

As contribution, Healthware takes under to upload the data in the information system of Medalyse, if it is possible within 1 workday, therefore our clients are free to reach and analyse the turnover data of NHIF on the 20th day after the given month.

Detailed description about the data published by OEP: link

Details about Medalyse: link

Product offering

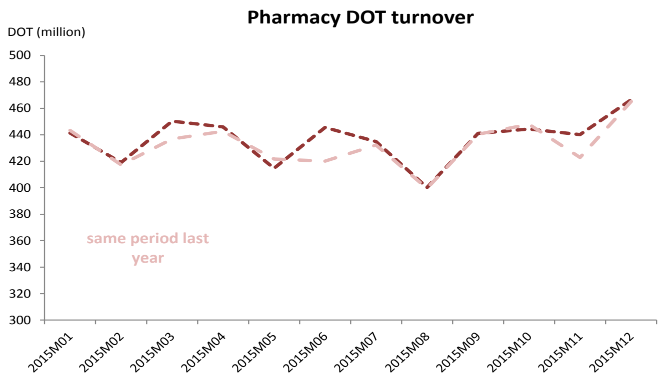
Changes to subsidised medicinal product categories

Changes in the public drug list	2015 Sep.	2015 Oct.	2015 Nov.	2015 Dec.	2016 Jan.	2016 Feb.	2016
Number of new products	22	34	23	8	28	9	37
Number of new AI	3	2	3	1	5	0	5
Number of delisted products	8	40	18	20	27	18	45
Prices							
Decrease	2	120	8	0	31	3	34
Increase	0	0	0	0	0	0	0

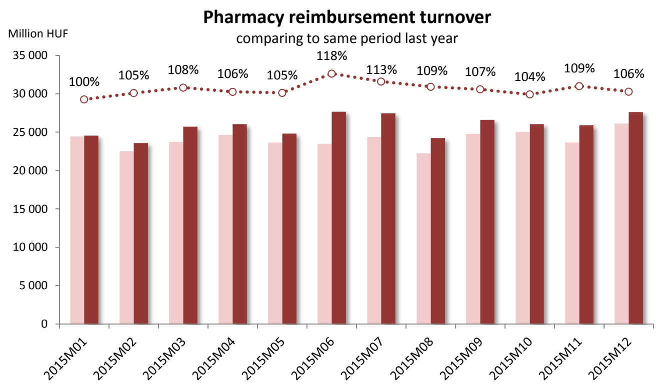
Changes in the public drug list	2015 Sep.	2015 Oct.	2015 Nov.	2015 Dec.	2016 Jan.	2016 Feb.	2016
Reimbursement							
Decrease	1	389	5	0	40	1	41
Increase	0	56	0	0	24	2	26
Co-payment							
Decrease	2	171	12	0	67	4	71
Increase	1	313	0	0	16	0	16

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 2015's reimbursement turnover, while only 0,36% of yearly DOT turnover.

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HEALTHWARE CONSULTING LTD.

Market data

Marketing authorisation information

2015	EMA	OGYI
New brands	89	185
New SKUs	871	2 143

2015 - Q4	EMA	OGYI
New brands	21	41
New SKUs	147	479

December 2015	EMA	OGYI
New brands	1	17
New SKUs	11	153

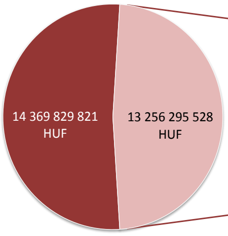
Source: Healthware analysis based on OGYI’s and EMA’s data

Average number of medical sales reps; 12/2015

All	1 668
Medicinal products	1 404
Medical aids	240
Both	24

Source: Healthware analysis based on OGYI’s

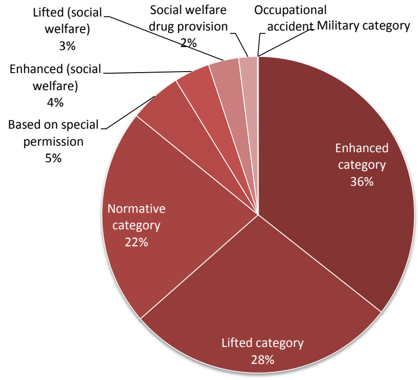
TOP10 DISTRIBUTOR by all reimbursement paid in December 2015



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 585 857 648 HUF
SANOFI-AVENTIS Zrt.	1 789 816 491 HUF
EGIS Gyógyszergyár Zrt.	1 385 624 564 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 340 926 087 HUF
TEVA Gyógyszergyár Zrt.	1 276 350 391 HUF
Pfizer Kft.	1 138 757 411 HUF
Novo Nordisk Hungária Kft.	1 030 347 938 HUF
Lilly Hungaria Kft.	971 030 433 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	878 164 806 HUF
Sandoz Hungária Kereskedelmi Kft.	859 419 760 HUF

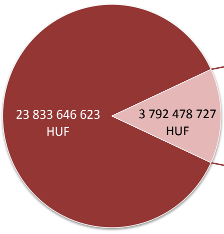
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 12/2015



Source: Healthware analysis based on the sales

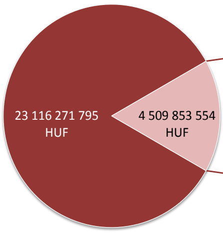
TOP10 BRAND by all reimbursement paid in December 2015



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	576 702 502 HUF
GLIVEC	Novartis Hungária Kft.	559 533 804 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing S	441 312 885 HUF
LANTUS	SANOFI-AVENTIS Zrt.	380 775 355 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H	380 180 583 HUF
HUMULIN	Lilly Hungaria Kft.	316 793 454 HUF
TECFIDERA	Biogen Idec Hungary Kft.	305 744 106 HUF
TASIGNA	Novartis Hungária Kft.	302 991 874 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	275 438 026 HUF
FOSTER	Chiesi Hungary Kft.	253 006 138 HUF

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

TOP10 ATC by all reimbursement paid in December 2015



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
V06D	other nutrients	626 263 990 HUF
B01AB05	enoxaparin	576 702 502 HUF
L01XE01	imatinib	559 533 804 HUF
N05AX13	paliperidone	515 544 837 HUF
C10AA07	rosuvastatin	445 729 507 HUF
A10AE04	insulin glargine	387 871 471 HUF
R03BB04	tiotropium bromide	380 180 583 HUF
A10AB01	insulin (human)	379 955 303 HUF
C09BA04	perindopril and diuretics	332 327 452 HUF
N07XX09	dimethyl fumarate	305 744 106 HUF

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

TOP10 ATC by number of patients in December 2015

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	362 074
C09BA04	perindopril and diuretics	299 649
C08CA01	amlodipine	273 902
C07AB12	nebivolol	256 981
C10AA05	atorvastatin	237 579
C10AA07	rosuvastatin	231 565
A02BC02	pantoprazole	228 617
M04AA01	allopurinol	212 069
A11CC05	colecalciferol	198 901
C09AA04	perindopril	184 540

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

Analysis of published list of reimbursement submissions in 2015 — Case study

Background

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 2015 only.

Method

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 2015 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 2015 within the subgroup of 60-day submissions. The table shows the number of submissions with 90 days and 60 days evaluation periods grouped according to reimbursement categories.

Type of submission	ATC	INN	Normative "Normatív"			Lifted "Emelt"				Enhanced "Kiemelt"			Itemized accounting "Tételes"			Special budget "Különkeret"		Sum			
			Reimbursed	Not yet appraised	Refused	Reimbursed	Not yet appraised	Refused	Extinctive	Reimbursed	Not yet appraised	Refused	Reimbursed	Not yet appraised	Extinctive	Reimbursed	Not yet appraised	Reimbursed	Not yet appraised	Refused	Extinctive
90 days	L01XE	protein kinase inhibitors									5			5					10		
90 days	L01XC	monoclonal antibodies												6					6		
90 days	A10AE	insulins and analogues for inj., long-acting				3	1			2	1							5	2		
90 days	B02BD	blood coagulation factors														2	1	2	1		
90 days	J05AX	other antivirals (direct acting antivirals: J05)														3		3			
90 days	S01LA	antineovascularisation agents												3					3		
90 days	J06BA	immunoglobulins, normal human											1	2				1	2		
90 days	R03AK	adrenergics in comb. with corticosteroids or other drugs, excl. anticholinergics					1	1											1	1	
60 days	V06D	other nutrients	4		2	3	1	1	1	3								10	1	3	1
60 days	N05AX12	aripiprazole								8								8			
60 days	N06AX21	duloxetine				8												8			
60 days	L01XX32	bortezomib											4		1			4			1
60 days	N05AH04	quetiapine								4								4			
60 days	N04BD02	rasagiline				4												4			
60 days	V06C	infant formulas	3															3			
60 days	J06BA02	normal human immunoglobulins											3					3			

Source: OEP

Results

In the year 2015, considering different drug formulations and dosages as one item, listing the brands, the National Health Insurance Fund received totally 180 submissions. The number of submissions with an evaluation period of 90 and 60 days were 79 (38%) and 129 (62%). From these 143 are reimbursed (90-day submissions: 27; 60-day submissions: 116), six were refused (90-day submission: 1; 60-day submissions: 5), and 52 were not yet appraised by the Insurance Fund at the time of the analysis (90-day submissions: 49; 60-day submissions: 3). Looking at the temporal distributions, most of the submissions arrived to the Payer in July and December (10-10), in other months of the year the average number of submission were 6.5.

In the case of the submissions with a 90 day evaluation period, the submissions included the following pharmaceutical preparations: anti-cancer drugs and antidiabetic drugs. No submissions were evaluated in the hospital drug reimbursement category. The average time from request to decision was 117 days in case of closed submissions (30). Ongoing procedures (49) were not considered when this average value was determined.

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: nutritionals, psycholeptics, psychoanaleptics, anti-cancer drugs and drugs for Parkinson's disease. The average time from request to decision was 36 days in case of closed submissions (126). Ongoing procedures (3) were not considered when this average value was determined.

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2015 - Q1	EMA	OGYI
New brands	25	42
New SKUs	143	542

2015 - H1	EMA	OGYI
New brands	42	87
New SKUs	603	1 060

2015	EMA	OGYI
New brands	89	185
New SKUs	871	2 143

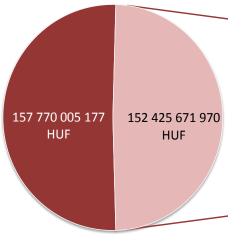
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 2015

All	1 711
Medicinal products	1 449
Medical aids	240
Both	21

Source: Healthware analysis based on OGYI's

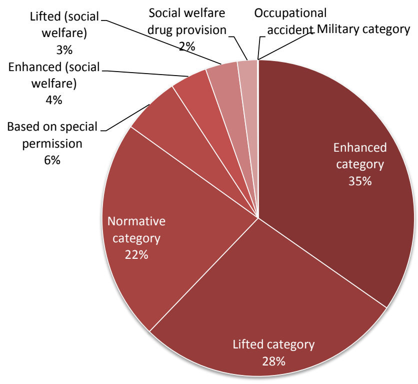
TOP10 DISTRIBUTOR by all reimbursement paid in 2015



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis (3 distributors)	30 230 487 236 HUF
SANOFI-AVENTIS Zrt.	19 519 429 503 HUF
EGIS Gyógyszergyár Nyrt.	15 406 321 240 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	14 749 723 439 HUF
Teva Magyarország Zrt.	14 253 608 801 HUF
Pfizer (4 forgalmazó)	13 555 303 467 HUF
JANSSEN-CILAG (3 distributors)	12 232 671 010 HUF
Novo Nordisk Hungária Kft. (2 distributors)	11 334 352 566 HUF
Eli Lilly (2 distributors)	11 220 520 528 HUF
Sandoz (2 distributors)	9 923 254 180 HUF

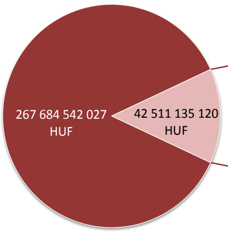
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 2015



Source: Healthware analysis based on the sales

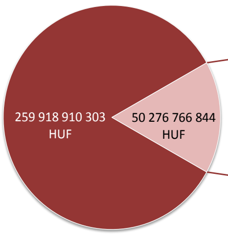
TOP10 BRAND by all reimbursement paid in 2015



TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	6 403 615 930 HUF
CLEXANE	SANOFI-AVENTIS Zrt.	6 393 304 288 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi M. Sz. Kft.	4 923 421 031 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H	4 684 249 633 HUF
LANTUS	SANOFI-AVENTIS Zrt.	4 122 246 229 HUF
HUMULIN	Lilly Hungaria Kft.	3 513 373 085 HUF
SUTENT	Pfizer Kft.	3 252 455 952 HUF
VIEKIRAX	AbbVie Kft.	3 238 204 055 HUF
TASIGNA	Novartis Hungária Kft.	3 002 057 318 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	2 978 207 599 HUF

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

TOP10 ATC by all reimbursement paid in 2015



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
V06D	other nutrients	6 569 714 544 HUF
L01XE01	imatinib	6 403 615 930 HUF
B01AB05	enoxaparin	6 393 304 288 HUF
N05AX13	paliperidone	5 803 273 949 HUF
C10AA07	rosuvastatin	4 889 421 409 HUF
R03BB04	tiotropium bromide	4 684 249 633 HUF
A10AB01	insulin (human)	4 263 365 587 HUF
A10AE04	insulin glargine	4 139 096 745 HUF
C09BA04	perindopril and diuretics	3 721 405 969 HUF
C10AA05	atorvastatin	3 409 318 790 HUF

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

TOP10 ATC by number of patients in 2015

TOP 10 - ATC	International non-proprietary name (INN)	Patients
J01CR02	amoxicillin and enzyme inhibitor	1 422 052
A11CC05	colecalciferol	801 495
J01FA10	azitromicin	775 139
B01AC06	acetylsalicylic acid	677 822
A02BC02	pantoprazole	562 363
C08CA01	amlodipine	531 199
C09BA04	perindopril and diuretics	524 531
J01MA12	levofloxacin	514 344
C07AB12	nebivolol	503 050
J01DC02	cefuroxim	494 584

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

Toplists based on the change of reimbursement amount; 2014/2015

By DISTRIBUTOR

TOP 5 increase	Reimbursement (HUF)		Change	
DISTRIBUTOR	2014	2015	Amount (HUF)	%
Novartis (3 distributors)	26 377 833 360	30 230 487 236	3 852 653 876	14,6%
AbbVie Kft.	1 554 264 072	5 276 471 704	3 722 207 632	239,5%
Biogen Idec (2 distributors)	3 372 340 939	5 452 152 687	2 079 811 748	61,7%
Aspen Pharma Trading Ltd.	67 535 021	1 757 824 014	1 690 288 994	2502,8%
JANSSEN-CILAG (3 distributors)	10 557 732 775	12 232 671 010	1 674 938 235	15,9%

TOP 5 decrease	Reimbursement (HUF)		Change	
DISTRIBUTOR	2014	2015	Amount (HUF)	%
GSK (8 distributors))	9 846 263 416	7 287 367 042	-2 558 896 374	-26,0%
AstraZeneca (2 distributors)	8 839 276 550	6 638 165 197	-2 201 111 353	-24,9%
Berlin-Chemie/A. Menarini	2 139 884 275	1 358 525 234	-781 359 041	-36,5%
Pharma-Regist Kft.	1 394 944 471	794 578 097	-600 366 373	-43,0%
Lundbeck Hungária Kft.	2 960 547 782	2 453 963 416	-506 584 366	-17,1%

By BRAND

TOP 5 increase		Reimbursement (HUF)		Change	
BRAND	Distributor	2014	2015	Amount (HUF)	%
VIEKIRAX	AbbVie Kft.	0	3 238 204 055	3 238 204 055	
TECFIDERA	Biogen Idec Hungary Kft.	306 659 996	2 592 644 196	2 285 984 200	745,4%
IMBRUVICA	JANSSEN-CILAG INTERNATIONAL NV	0	1 381 294 350	1 381 294 350	
STIVARGA	Bayer Pharma AG	8 119 762	1 315 725 444	1 307 605 682	16104,0%
BUFOMIX	ORION PHARMA Kft.	245 633 154	1 133 570 118	887 936 964	361,5%

TOP 5 decrease		Reimbursement (HUF)		Change	
BRAND	Distributor	2014	2015	Amount (HUF)	%
SYMBICORT	AstraZeneca	4 348 434 374	2 061 211 894	-2 287 222 480	-52,6%
CIPRALEX	Lundbeck Hungária Kft.	1 504 020 052	383 872 484	-1 120 147 567	-74,5%
SERETIDE	GlaxoSmithKline Kft.	2 816 119 396	1 756 455 080	-1 059 664 316	-37,6%
INEGY	MSD Pharma Hungary	1 282 729 823	426 401 101	-856 328 722	-66,8%
SEROQUEL	AstraZeneca	1 701 633 171	874 908 543	-826 724 628	-48,6%

By BRAND (exluding reimb. turnover which based on special permission)

TOP 5 increase		Reimbursement (HUF)		Change	
BRAND	Distributor	2014	2015	Amount (HUF)	%
TECFIDERA	Biogen Idec Hungary Kft.	276 183 470	2 592 644 196	2 316 460 726	838,7%
GILENYA	Novartis Hungária Kft.	1 157 143 326	2 062 074 870	904 931 544	78,2%
BUFOMIX	ORION PHARMA Kft.	245 633 154	1 133 570 118	887 936 964	361,5%
XARELTO	Bayer Hungária K. és Sz. Kft.	1 249 711 947	1 975 633 631	725 921 685	58,1%
XEPLION	Janssen-Cilag Gy.ker.-i M. Sz. Kft.	4 198 189 218	4 923 421 031	725 231 813	17,3%

TOP 5 decrease		Reimbursement (HUF)		Change	
BRAND	Distributor	2014	2015	Amount (HUF)	%
SYMBICORT	AstraZeneca	4 348 434 374	2 061 211 894	-2 287 222 480	-52,6%
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By INN

TOP 5 increase		Reimbursement (HUF)		Change	
BRAND	Distributor	2014	2015	Amount (HUF)	%
VIEKIRAX	AbbVie Kft.	0	3 238 204 055	3 238 204 055	
TECFIDERA	Biogen Idec Hungary Kft.	306 659 996	2 592 644 196	2 285 984 200	745,4%
IMBRUVICA	JANSSEN-CILAG INTERNATIONAL NV	0	1 381 294 350	1 381 294 350	
STIVARGA	Bayer Pharma AG	8 119 762	1 315 725 444	1 307 605 682	16104,0%
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SERETIDE	GlaxoSmithKline Kft.	2 816 119 396	1 756 455 080	-1 059 664 316	-37,6%
INEGY	MSD Pharma Hungary	1 282 729 823	426 401 101	-856 328 722	-66,8%
SEROQUEL	AstraZeneca	1 701 633 171	874 908 543	-826 724 628	-48,6%

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