No.11, Issue III. November 2015
Published: 27 November 2015

Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE CONSULTING LTD.

News, current issues

- **Legislations** come into force between 01/10/2015 and 01/11/2015: Act LXXXIII of 1997 (01.11.2015); Act CLIV of 1997 (28.10.2015); Act XCVIII of 2006 (01.10.2015); Gov.Decree No.43/1999. (01.10.2015); Gov.Decree No.16/2012. (01.11.2015); Gov.Decree No.46/2012. (01.11.2015); ESzCsM Decree No.32/2004. (01.11.2015); ESzCsM Decree No.44/2004. (20.10.2015); EüM Decree No.5/2004. (20.10.2015); EüM Decree No.43/2005. (20.10.2015); EüM Decree No.52/2005. (20.10.2015); EüM Decree No.14/2007. (20.10.2015); EüM Decree No.41/2007. (20.10.2015); NEFMI Decree No.11/2011. (20.10.2015); EMMI Decree No.15/2012. (20.10.2015)
- **NEWS:** *"Compassionate use programme in Hungary"* link
- **NEWS:** *"Debt settlement of hospitals could be canceled this year"* link
- **NEWS:** *"E-health: NHIF is in the home stretch"* link
- **NEWS:** *"The proper care of patients is common interest of the Government and manufacturers"* link
- **NEWS:** *"Get what we deserve? Report on healthcare's wages"* link
- **STUDY:** *"Health at a Glance 2015"* 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-IX. months	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 907,1**	**1 910,8**	**1 444,8**	**100,8%**	**102,2%**
Curative preventive provisions	945,6	948,6	706,9	99,4%	101,1%
Medicine subsidies	302,3	298,1	240,0	107,4%	107,3%
Medicine subsidies (pharmacy)	286,4	224,4	231,2	137,4%	108,5%
Total of Budgetary Revenues	**1 907,1**	**1 910,8**	**1 442,4**	**100,6%**	**100,0%**
Social Security Contributions	896,3	1 198,5	911,0	101,3%	135,8%
Contribution of Pharmaceutical Manufacturers and Wholesalers	57,4	58,0	49,4	113,7%	113,4%
Balance	**0,0**	**0,0**	**-2,4**		**0,0%**

The 2015 budget counts with 0,2% increase in the expenditure and in the revenues too, while the balance is nil. The central budget contribution is planned to be less with 35,1% than last year fulfilment, and this gap is filled with the 33,7% higher social security contribution (302 billion HUFs). The medicine subsidies plan are lower with 4,2 billion HUFs than last year expenses.
In the first nine months of 2015 the Health Security Fund produced a 0,17% deficit. Medicine subsidies shows 7,4% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission.

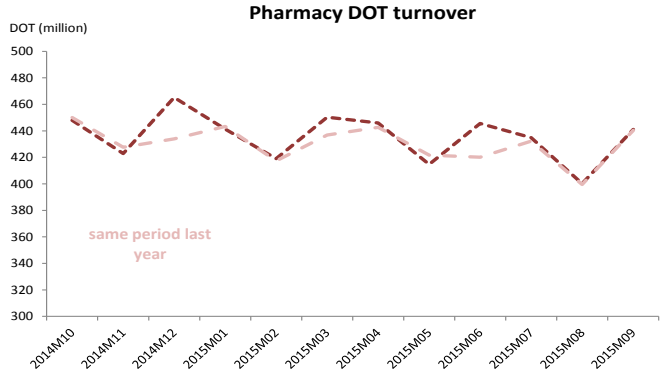
Changes to subsidised medicinal product categories

Changes in the public drug list	2015 June	2015 July	2015 Aug.	2015 Sep.	2015 Oct.	2015 Nov.	2015
Number of new products	16	12	34	22	34	23	272
Number of new AI	2	2	4	3	2	3	29
Number of delisted products	30	16	16	8	40	18	295
Prices							
Decrease	0	42	5	2	120	8	378
Increase	0	5	0	0	0	0	11

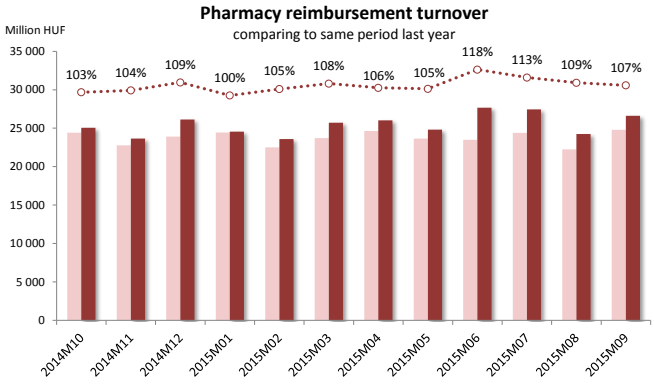
Changes in the public drug list	2015 June	2015 July	2015 Aug.	2015 Sep.	2015 Oct.	2015 Nov.	2015
Reimbursement							
Decrease	71	4	1	1	389	5	918
Increase	6	0	0	0	56	0	145
Co-payment							
Decrease	47	7	2	2	171	12	556
Increase	34	0	1	1	313	0	653

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

While the turnover of reimbursed medicines in pharmacies increased by 2,74% in 2014 (measured in DOT), the total medicine subsidy of Health Security Fund was higher by 2,21%. The subsidy of new INNs (got reimbursed status in 2014) was 1,26% of the yearly total, while its turnover was only 0,03% of the yearly DOT turnover.
Drug sales in the first nine months of 2015 was 0,96% higher than the same period last year, while the average reimbursement per DOT decreased with 0,45% compared to the previous month and was higher with 8,42% than the last year's average. The reimbursement turnover is 6,50% higher for this period compared to last year.

HealthWare Consulting Ltd.
1093 Budapest, Közraktár street 32. 7th floor (RiverPark Offices) | +36 1 324 2050 | **www.healthware.hu**

Newsletter

Actualities of Hungarian pharmaceutical market

No.11, Issue III. November 2015
Published: 27 November 2015

Market data

Marketing authorisation information

2014	EMA	OGYI
New brands	70	182
New SKUs	359	1 881

2015 - Q3	EMA	OGYI
New brands	26	52
New SKUs	310	553

September 2015	EMA	OGYI
New brands	9	11
New SKUs	50	131

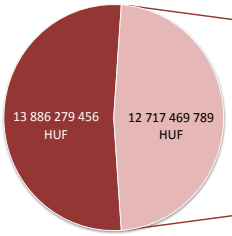
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 09/2015

All	1 709
Medicinal products	1 467
Medical aids	228
Both	14

Source: Healthware analysis based on OGYI's

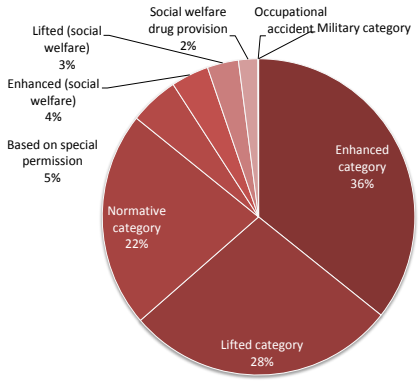
TOP10 DISTRIBUTOR by all reimbursement paid in September 2015



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 492 921 499 HUF
SANOFI-AVENTIS Zrt.	1 666 623 241 HUF
EGIS Gyógyszergyár Zrt.	1 306 411 758 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 264 282 971 HUF
TEVA Gyógyszergyár Zrt.	1 219 438 281 HUF
Pfizer Kft.	1 116 307 865 HUF
Novo Nordisk Hungária Kft.	968 370 102 HUF
Lilly Hungaria Kft.	963 081 578 HUF
Sandoz Hungária Kereskedelmi Kft.	869 259 714 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	850 772 779 HUF

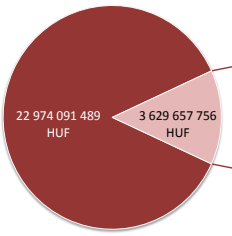
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 09/2015



Source: Healthware analysis based on the sales

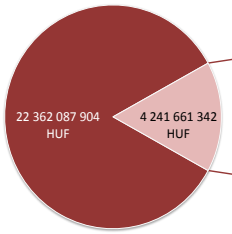
TOP10 BRAND by all reimbursement paid in September 2015



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	541 830 162 HUF
GLIVEC	Novartis Hungária Kft.	536 823 734 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing S	432 065 109 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H	390 967 782 HUF
LANTUS	SANOFI-AVENTIS Zrt.	353 009 472 HUF
HUMULIN	Lilly Hungaria Kft.	303 267 865 HUF
SUTENT	Pfizer Kft.	285 140 782 HUF
TASIGNA	Novartis Hungária Kft.	274 438 256 HUF
TECFIDERA	Biogen Idec Hungary Kft.	256 482 644 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	255 631 950 HUF

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

TOP10 ATC by all reimbursement paid in September 2015



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
V06D	other nutrients	545 947 987 HUF
B01AB05	enoxaparin	541 830 162 HUF
L01XE01	imatinib	536 823 734 HUF
N05AX13	paliperidone	506 546 433 HUF
C10AA07	rosuvastatin	412 884 101 HUF
R03BB04	tiotropium bromide	390 967 782 HUF
A10AB01	insulin (human)	360 723 800 HUF
A10AE04	insulin glargine	353 386 188 HUF
C09BA04	perindopril and diuretics	307 410 374 HUF
L01XE04	sunitinib	285 140 782 HUF

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

TOP10 ATC by number of patients in September 2015

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	353 506
C09BA04	perindopril and diuretics	284 160
C08CA01	amlodipine	263 904
C07AB12	nebivolol	243 407
C10AA05	atorvastatin	233 766
C10AA07	rosuvastatin	218 676
A02BC02	pantoprazole	209 467
M04AA01	allopurinol	204 878
C09AA04	perindopril	175 808
A11CC05	colecalciferol	170 848

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

Methodological difficulties of compliance analyses based on real-world data — Case study

The research epitomized below was presented at the ISPOR conference 2015 by Healthware[1] and it is about the methodological difficulties of compliance analyses. The patients' adherence pattern, considering the regular filling of their prescribed therapy, is a key factor of therapeutic effectiveness of medication treatments, applied in case of chronic diseases. The therapy effectiveness, increased in course of appropriate patient-adherence, may grant direct or indirect advantages for all stakeholders of the health care system.

Regarding adherence analysis numerous ratios can be found in international scientific literature with simpler or more complex methodology, and it is essential to know the difficulties and pitfalls of the data management and methodology to the objective assessment of the chosen ratio. The chief aim of our study to demonstrate factors in course of practical examples in three indication areas, which may substantially influence the results and the right conclusions, if these factors are modified. The adherence analysis is based on prescription filling data of database of the Hungarian Health Fund in the field of the following indications: diabetes, COPD, prostate cancer.

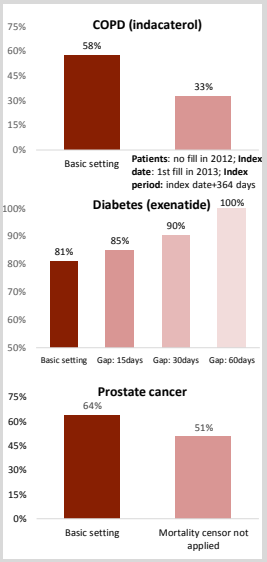
From the ratios available in scientific literature, the methodology of PDC (Proportion of Days Covered)[2] was chosen as a basis, which is such a ratio, which compares the number of therapy-covered days to the number of days that can be spent theoretically on the therapy in a given period. The value of the PDC ratio is ranging between 0 and 1, where 1 means complete therapy coverage. In course of the indications a basic setting was established to calculate PDC ratio, then after changing each specified parameter one by one (ceteris paribus), the ratio was recalculated. The basic settings and the modifications are shown in the table, and the results of the analysis with the basic settings and after the modifications in each indication are presented on the figures.

Parameters	Basic setting	Modification
Patient inclusion and exclusion criteria	At least 1 therapy-covered day in 2013	**COPD:** no fill in 2012
Observation period	01.01.2012 - 31.12.2014	-
Index date	1st therapy-covered day in 2013	**COPD:** 1st fill in 2013
Index period	From index date to 31.12.2013	**COPD:** index date + 364 days or death
Mortality	If death occured within index period, medication vectors and end of period are truncated	**Prostate:** death is not considered
Oversupply	Therapy vectors overlapping a new fill or end of index period are truncated	-
Gap (grace period)	1 day	**Diabetes:** 15, 30, 60 days
DDD	Based on SPC DDD and dosing	-

In case of the modified settings considering **COPD (indacaterol)** (top) the therapy coverage was examined only in case of new patients in 2013 (no indacaterol fills observed in 2012), the index period was the period from the first fill + 364 days (or death, if it occured within the 364 days). It is displayed on left-side figure that more than 20% -point difference can be observed between the two median PDC ratios calculated by the two approaches, in case of basic setting the PDC ratio is close to 60%, while with the modified setting it is 33%. The chief cause of the difference, that the new patients starting indacaterol therapy in the second half of 2013 have less theoretically chance to drop out or switch off until the end of the index period, thus they pull up aggregated median value. The result calculated based on the modified parameter reflects the practical and real therapy coverage ratio better compared to the basic setting, based on the results implementation of this modification in course of calculation PDC ratio is adequate.

In case of **diabetes (exenatide)** (middle) the grace period was modified, the strict 1 day value based on the basic setting was eased to 15, 30 and 60 days. The PDC ratio resulted a value above 80% in case of the basic setting, by softening the gap with 15, 30 and 60 days the ratio increased to 85% and 90%, then reached the 100% median value. Modifying the gap we eased the strictness requirements, it is worth determining the level of strictness based on the specificities and characteristics of the indication area in course of PDC calculation.

In case of **prostate cancer (goserelin)** (bottom) the mortality parameter was modified, if a patient died within the index period, then neither the part of the therapy vector overlapping after death (nominator), nor the period between death and the end of index period (denominator) was truncated. Based on the results the mortality as a parameter should be managed in course of PDC calculation, censoring the time period after death is required in course of calculation both nominator and denominator.



Based on the results it may be concluded, that no general best practice can be observed, all settings have both advantages and limitations. It may be worth choosing the key parameters considering the specialties of each indication in order to draw conclusions as correct as possible with the focus of the original aim of the study.

1 Péter Andriska, Tamás Komáromi, Róbert Frigyesy, Balázs Salfer (November 2015) - Methodological Difficulties of Compliance Analyses Based on Real-World Data, Poster presented at ISPOR 18th Annual European Congress, Milan

2 Sudeep Karve, BPharm, MS, Mario A. Cleves, PhD, Mark Helm, MD, Teresa J. Hudson, PharmD,Donna S. West, RPh, PhD, Bradley C. Martin, PharmD, PhD - Prospective Validation of Eight Different Adherence Measures for Use with Administrative Claims Data among Patients with Schizophrenia, Value In Health, 2009, Volume 12.

HealthWare Consulting Ltd.

1093 Budapest, Közraktár street 32. 7th floor (RiverPark Offices) | +36 1 324 2050 | **www.healthware.hu**