Newsletter

HEALTHWARE
CONSULTING LTD.

News, current issues

● **Legislations** come into force from April 2013: Act CLIV of 1997 (2013.04.29.); EüM Decree No. 31/2010. (2013.04.01.); ESzCsM Decree No. 32/2004. (2013.04.01.); Gov.Decree No. 323/2010. (2013.04.29.); Gov.Decree No. 337/2008. (2013.04.29.); Gov.Decree No. 43/1999. (2013.04.27.); Gov.Decree No. 59/2011. (2013.04.29.); NM Decree No. 9/1993. (2013.04.01.); Act XCV of 2005 (2013.04.29.)

● **NEWS:** *„The result of the first centralised medicine tender is available"* link

● **NEWS:** *„Healthcare Fund recorded a strong surplus of 40 billion HUF till the end of the period from January to April"* link

● **NEWS:** *„Director-general of GYEMSZI: This year will be the year of struggle in the area of healthcare"* link

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Billion HUF

Health Security Fund	2012. I-XII.	2013 original appropriation	2013		
			I-III.	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 791,3**	**1 804,3**	**436,7**	**96,8%**	**102,4%**
Curative preventive provisions	842,1	880,6	204,6	93,0%	108,9%
Medicine subsidies	315,1	280,0	72,5	103,6%	859,8%
Total Of Budgetary Revenues	**1 744,3**	**1 804,3**	**464,8**	**103,0%**	**108,3%**
Social Security Contributions	854,2	727,0	189,0	104,0%	93,4%
Contribution of Pharmaceutical Manufacturers and Wholesalers	75,0	49,0	16,5	134,9%	71,4%
Balance	**-47,0**	**0,0**	**28,0**		**1007,2%**

The 2013 budget counts with 0,7% increase in the expenditure and 3,4% increase in the revenues, while the balance is nil. The social security contribution is planned to be less with 15% than last year fulfilment, and this gap is filled with central budget contribution. The medicine subsidies plan are lower with 11% than last year expenses but higher with 2 billion HUF than last year budget plan.

In the first three months of 2013 the Health Security Fund produced a significant surplus thanks to the higher revenues (+3%) and the lower expenses (-3,2%) compared to the original budget appropriation.
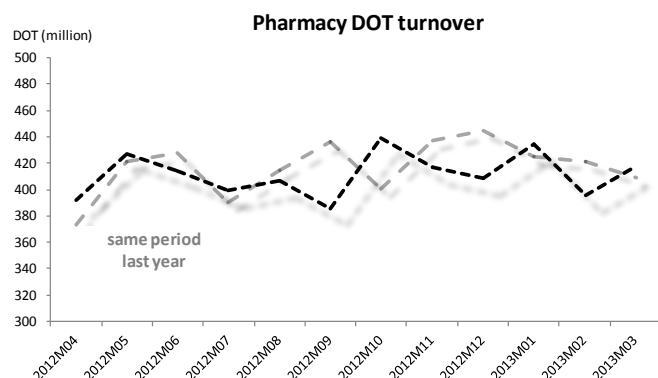
Changes to subsidised medicinal product categories

Changes in the public drug list	2012 Dec.	2013 Jan.	2013 Feb.	2013 Mar.	2013 Apr.	2013 May	2013
Number of new products	33	43	34	26	30	54	187
Number of new AI	0	2	0	5	3	1	11
Number of delisted products	14	88	19	20	74	59	260
Prices							
Decrease	11	61	13	14	712	7	807
Increase	1	0	0	1	1	0	2

Changes in the public drug list	2012 Dec.	2013 Jan.	2013 Feb.	2013 Mar.	2013 Apr.	2013 May	2013
Reimbursement							
Decrease	4	71	7	16	1 346	20	1 460
Increase	0	4	0	3	224	0	231
Co-payment							
Decrease	16	107	18	27	858	26	1 036
Increase	3	22	0	1	813	2	838

Source: Healthware analysis based on OEP-PUPHA data

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

Pharmacy DOT turnover

DOT (million)

same period last year

Source: Healthware analysis based on OEP's data

Pharmacy reimbursement turnover
comparing to same period last year

Million HUF

82% 82% 77% 85% 81% 73% 92% 79% 76% 83% 84% 94%
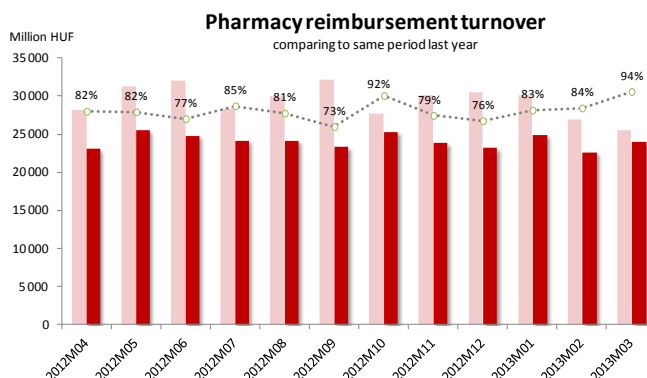
Source: Healthware analysis based on OEP's data

While the turnover of reimbursed medicines in pharmacies decreased by 1,6% in 2012 (measured in DOT), the total medicine subsidy of Health Security Fund was lower by 17%. The main causes of this saving were the reallocation of the drug budget (expensive therapies were transferred to the hospital budget), and the new process of reference price system which lead to significant cuts in prices and reimbursements.

Drug sales in the first quarter of 2013 was 0,7% lower than the same period last year, while the average reimbursement per DOT remained the same level as from the last reference price procedure.

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Market data

Marketing authorisation information

2012	EMA	OGYI	2013 - Q1	EMA	OGYI	March 2013	EMA	OGYI
New brands	64	427	New brands	16	72	New brands	5	26
New SKUs	798	4 230	New SKUs	204	577	New SKUs	89	221

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

Average number of medical sales reps; 03/2013

All	1 811
Medicinal products	1 550
Medical aids	229
Both	32

Source: Healthware analysis based on OGYI's

TOP10 MAH by all reimbursement paid in March 2013

15 068 574 928 HUF 63%
8 890 504 779 HUF 37%

TOP 10 - MAH	Reimbursement
Novartis Europharm Limited	1 371 288 534 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 156 481 148 HUF
EGIS Gyógyszergyár Nyrt.	1 112 608 113 HUF
SANOFI-AVENTIS Zrt.	916 375 464 HUF
Eli Lilly Nederland B. V.	882 237 581 HUF
GlaxoSmithKline Kft.	781 274 396 HUF
Novo Nordisk A/S	769 637 772 HUF
Boehringer Ingelheim International GmbH	667 337 666 HUF
AstraZeneca Kft.	634 734 478 HUF
Novartis Hungária Kft.	598 529 629 HUF

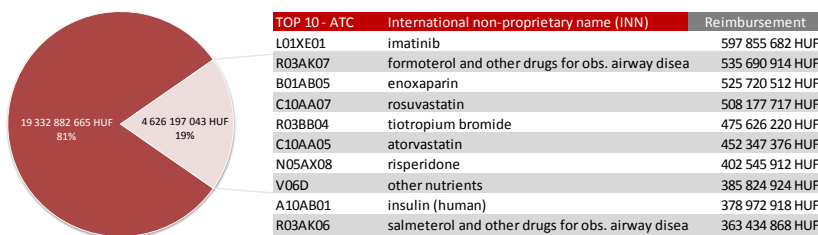*Source: Healthware analysis based on the sales turnover that pharmacies produced from POM*
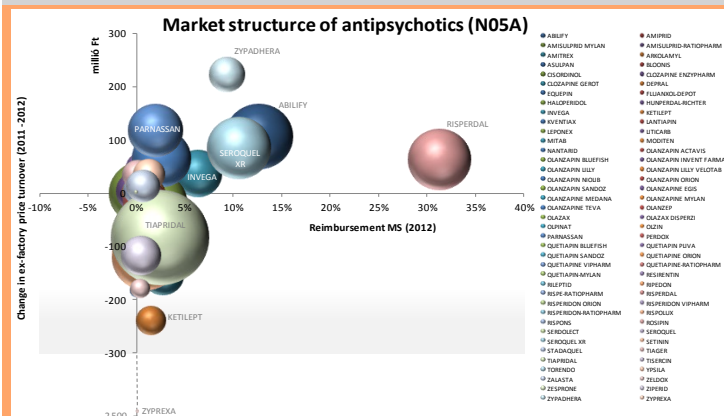
TOP10 BRAND by all reimbursement paid in March 2013

20 236 512 324 HUF 84%
3 722 567 384 HUF 16%

TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	597 855 682 HUF
CLEXANE	SANOFI-AVENTIS Zrt.	525 720 512 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b.	475 626 220 HUF
SYMBICORT	AstraZeneca Kft.	380 320 682 HUF
RISPERDAL	Janssen-Cilag Kft.	375 186 110 HUF
SERETIDE	GlaxoSmithKline Kft.	316 416 254 HUF
HUMULIN	Lilly Hungaria Kft.	309 775 217 HUF
LANTUS	SANOFI-AVENTIS Zrt.	268 928 235 HUF
SUTENT	Pfizer Kft.	253 418 300 HUF
COVEREX	EGIS Gyógyszergyár Nyrt.	219 320 172 HUF

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

TOP10 ATC by all reimbursement paid in March 2013

19 332 882 665 HUF 81%
4 626 197 043 HUF 19%

TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
L01XE01	imatinib	597 855 682 HUF
R03AK07	formoterol and other drugs for obs. airway disea	535 690 914 HUF
B01AB05	enoxaparin	525 720 512 HUF
C10AA07	rosuvastatin	508 177 717 HUF
R03BB04	tiotropium bromide	475 626 220 HUF
C10AA05	atorvastatin	452 347 376 HUF
N05AX08	risperidone	402 545 912 HUF
V06D	other nutrients	385 824 924 HUF
A10AB01	insulin (human)	378 972 918 HUF
R03AK06	salmeterol and other drugs for obs. airway disea	363 434 868 HUF

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

Drug reimbursement by legal title; 03/2013

- Public health care 3%
- Based on special permission 1%
- Occupational accident Military category
- Enhanced public healthcare 4%
- Lifted public healthcare 4%
- Enhanced category 34%
- Normative category 26%
- Lifted category 28%

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

Market structure change of antipsychotics market (2011-2012) — Case study

Market structure of antipsychotics (N05A)

In course of the following case study we examined the market structure of the antipsy-chotics market (ATC4: N05A) between 2011 and 2012. The market was considered as a market with lots of market players, almost 80 brands had reimbursed turnover in the two years. Market of some active substances became a generic market, in other cases the patent status of the original products still exists. In case of these typically 100% reimbursed active substances, the blind bid system, introduced in the end of 2011 meant a significant breakpoint in market patterns, the changes had large impact on the turnover ratios, size of market shares, number of market players. In course of the analysis we examined, what direction the antipsychotic market trends were led to by the introduction of the process, generating price competition. The following pattern was set up as a null-hypothesis of the analysis: the market is price-sensitive (HUF300 unit price), turnover of products, taking active role in price competition increases, turnover of original products decreases in case of active substances, concerned in blind bid process, and total turnover of active substances with lower price level due to blind bid increases.

On the chart above the reimbursement based market share in 2012 (Axis X), the yearly change of ex-factory price turnover (Axis Y), and relative growth of DOT turnover (bubbles) can be observed. It is displayed, that original brands with patent and high reimbursement outflow, and the large generic products could realize definite and significant sales increase. Standard deviation can be considered high, the mean amounts close to minus HUF 10 Mn. Original products concerned in FX process and products of large generic manufacturers realized sales decrease, larger more than double of the standard deviation. Change of sales of smaller generic products is scattered around zero. In case of oral olanzapine the original product did not entered price competition at the first blind bid, and delisted from reimbursement.

The null-hypothesis, that co-payment of antipsychotics is price-sensitive, and that smaller generic distributors, generating price competition manage to acquire a remarkable part of the market due to price cuts and increase sales, and that role of active substances, got over strong price erosion increases in prescribing patterns, cannot be confirmed. Based on the pattern on the chart, it can be concluded, that the price is not the only factor, that determines market trends, a more complex analysis is needed to discover the other key factors.

Further research directions are feasible in order to implement a more complex examination of market structure patterns:
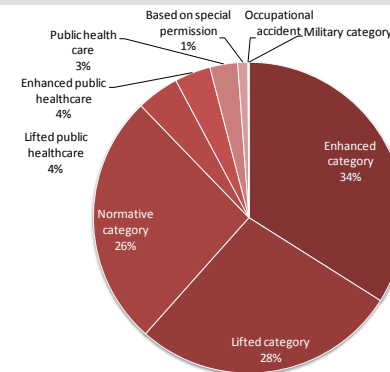- Separating original/generic market
- Price elasticity, price sensitivity of co-payments
- Prescribing pattern of specialists, therapy switches, distribution of refillings by ICD code, therapy-compliance, therapy persistence based on real OEP (NHIFA) data