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Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE CONSULTING LTD.

News, current issues

- **Legislations** come into force from November 2014**:** NEFMI Decree No.12/2011. (2014.11.11.)
- **NEWS:** *"OEP announced 10 guidance proposals"* link
- **NEWS:** *"Some significant changes in health care are around the corner"* link
- **NEWS:** *"Hungarians spend a lot on health-related expenses"* link
- **NEWS:** *"A new government agency takes it all"* link
- **STUDY:** *"TÁRKI - Social Report 2014"* link

Revealing real symptoms of diseases

In the analysis basic country-wide demographic data related to diseases (prevalence, incidence, mortality rates) are summarized. Along with randomly chosen subcategories (area, sex, primary disease, accompanying diseases [comorbidity])
As a result of the analysis, the basic epidemiological characteristics of a given therapeutic area can be brought to light, which may provide a good starting point to any further research, or may be suitable for independent use, especially in professional material to the attention of physicians. Because there is no publicly accessible central patients' register, only limited disease-related data and information is available. Consequently these pieces of information can play a valuable role on their own.

Further information about the service: link

Product offering

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Billion HUF

Health Security Fund	2013. I-XII.	2014 original appropriation	2014		
			I-X. months	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 847,8**	**1 884,2**	**1 565,9**	**99,7%**	**105,4%**
Curative preventive provisions	908,0	931,9	771,3	99,3%	109,0%
Medicine subsidies	296,0	294,1	249,7	101,9%	102,4%
Medicine subsidies (pharmacy)	281,5	222,4	237,9	128,4%	101,8%
Total of Budgetary Revenues	**1 847,8**	**1 884,2**	**1 600,7**	**101,9%**	**103,8%**
Social Security Contributions	768,0	852,9	744,5	104,8%	117,2%
Contribution of Pharmaceutical Manufacturers and Wholesalers	58,7	56,0	48,4	103,6%	95,4%
Balance	**0,0**	**0,0**	**34,9**		**61,7%**

The 2014 budget counts with 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 5% than last year fulfilment, and this gap is filled with the 11% higher social security contribution (85 billion HUF). The medicine subsidies plan are lower with 2 billion HUF than last year expenses.
In the first ten months of 2014 the Health Security Fund produced a 2,22% surplus mainly because of the higher social security contributions (+4,8%).

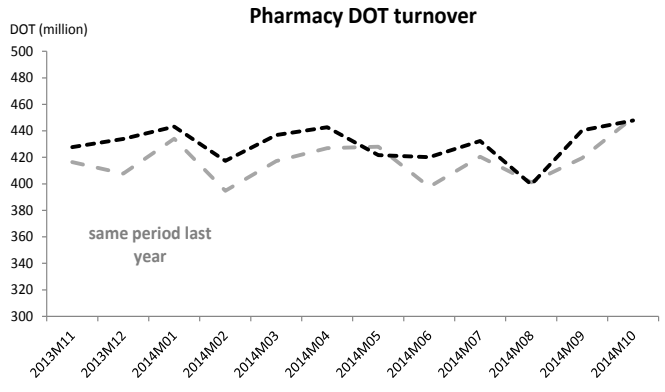
Changes to subsidised medicinal product categories

Changes in the public drug list	2014 July	2014 Aug.	2014 Sep.	2014 Oct.	2014 Nov.	2014 Dec.	2014
Number of new products	18	21	26	23	13	8	237
Number of new AI	4	3	1	1	1	1	23
Number of delisted products	29	26	20	47	23	9	365
Prices							
Decrease	46	10	7	263	3	3	736
Increase	0	1	2	2	0	2	60

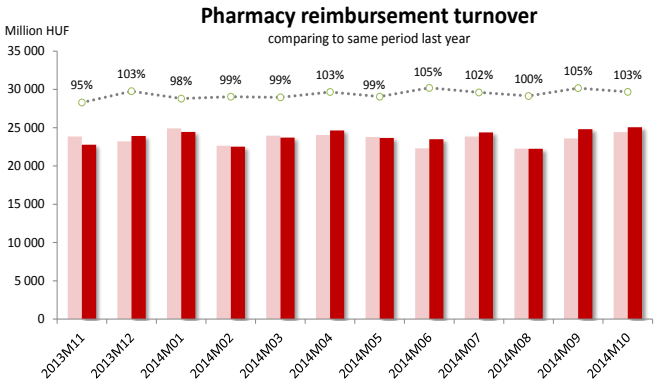
Changes in the public drug list	2014 July	2014 Aug.	2014 Sep.	2014 Oct.	2014 Nov.	2014 Dec.	2014
Reimbursement							
Decrease	87	11	2	683	1	2	1 716
Increase	2	2	0	78	1	6	309
Co-payment							
Decrease	61	18	9	348	7	4	1 065
Increase	41	2	2	511	0	5	1 233

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 or reimbursed medicines in pharmacies increased by 2,2% in 2013 (measured in DOT), the total medicine subsidy of Health Security Fund was lower by 5,9%. The main cause of this saving was the reference price system which lead to significant cuts in prices and reimbursements.
Drug sales in the first ten months of 2014 was 2,65% higher than the same period last year, while the average reimbursement per DOT increased slightly compared to the previous month. The reimbursement turnover is 1,34% higher for this period compared to last year.

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Market data

Marketing authorisation information

2013	EMA	OGYI
New brands	80	207
New SKUs	719	1 776

2014 - Q3	EMA	OGYI
New brands	14	43
New SKUs	117	332

October 2014	EMA	OGYI
New brands	1	16
New SKUs	8	86

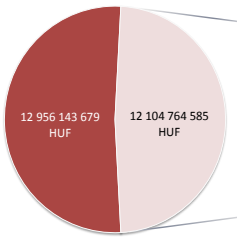
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 10/2014

All	1 827
Medicinal products	1 558
Medical aids	234
Both	35

Source: Healthware analysis based on OGYI's

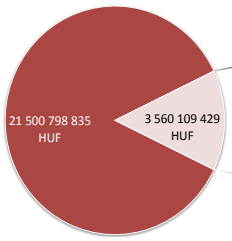
TOP10 DISTRIBUTOR by all reimbursement paid in October 2014



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 276 314 039 HUF
SANOFI-AVENTIS Zrt.	1 594 356 515 HUF
EGIS Gyógyszergyár Zrt.	1 279 523 175 HUF
TEVA Gyógyszergyár Zrt.	1 261 124 783 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 188 974 303 HUF
Pfizer Kft.	1 039 079 525 HUF
Lilly Hungaria Kft.	943 696 680 HUF
Novo Nordisk Hungária Kft.	903 902 814 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	822 647 276 HUF
Sandoz Hungária Kereskedelmi Kft.	795 145 476 HUF

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

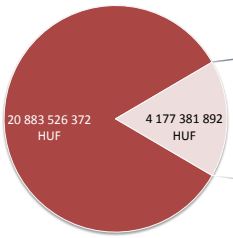
TOP10 BRAND by all reimbursement paid in October 2014



TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	567 995 850 HUF
CLEXANE	SANOFI-AVENTIS Zrt.	516 250 786 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H. N	425 395 584 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing Szo	368 741 154 HUF
LANTUS	SANOFI-AVENTIS Zrt.	341 962 944 HUF
HUMULIN	Lilly Hungaria Kft.	297 549 458 HUF
SUTENT	Pfizer Kft.	284 844 669 HUF
SYMBICORT	AstraZeneca Kft.	279 656 387 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	245 390 437 HUF
RISPERDAL	Janssen-Cilag Gyógyszerkereskedelmi Marketing Szo	232 322 159 HUF

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

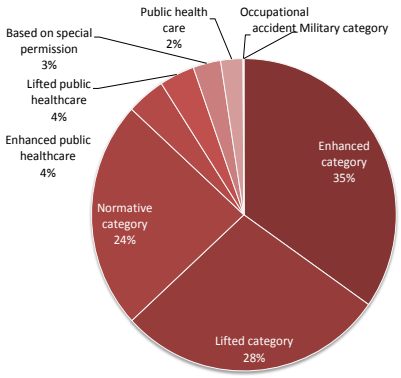
TOP10 ATC by all reimbursement paid in October 2014



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
L01XE01	imatinib	567 995 850 HUF
B01AB05	enoxaparin	516 250 786 HUF
V06D	other nutrients	486 543 521 HUF
N05AX13	paliperidone	449 280 882 HUF
R03BB04	tiotropium bromide	425 395 584 HUF
C10AA07	rosuvastatin	391 816 522 HUF
A10AB01	insulin (human)	367 601 371 HUF
A10AE04	insulin glargine	341 962 944 HUF
R03AK07	formoterol and other drugs for obs. airway diseases	327 940 808 HUF
C10AA05	atorvastatin	302 593 624 HUF

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

Drug reimbursement by legal title; 10/2014



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

Comparison of efficiency of different therapies on observational data — Case study

Randomized controlled trial is a frequently used method for comparing the efficiency of two therapies. In this method, patients are randomly selected into two therapy groups (*A* and *B*) by given probability before following them in the study period. The randomization reduces the systematic differences between the characteristics of the two groups making the efficiency of these therapies directly comparable. Although the comparison is straightforward, the method often cannot be performed due to financial-, ethical-, or other reasons. Therefore observational studies have become popular recently, when the statistical analysis of the patients' path is simply based on real, historical records. An observational study is a retrospective method by definition, which does not require any intervention in the patients' path or any specific preliminary design. Typically, the database of the National Health Insurance Fund Administration, hospital registries or any patient support database can be used as data source for such studies.

Observational studies require cautious preparations as - unlike in randomized controlled trials - the demographical characteristics, patient pathways or drug administration protocols affect therapy assignment. This fact can cause significant differences between the populations of the different therapy groups, thus the results of the comparison can be often interpreted only as association. In some cases these associative measures are far sufficient for comparing populations or predicting costs, although in this form they are not appropriate for revealing causal effects. There is a risk that the differences obtained by the comparison are occurred not only due to the real effects of the therapies, but the therapy-inhomogeneity within the population. E.g. in practice, if in a therapy group the rate of patients with high mortality (severe state) is much higher than in another one, then the raw estimation of the effect of therapies on mortality may be strongly biased.

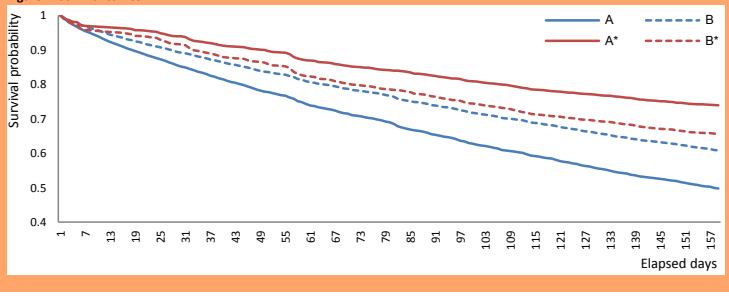
The propensity method can reduce the bias of the abovementioned case. In this method, the patients are divided into so-called propensity-subgroups, by estimating the probabilities of being treated by therapy *A* or *B*. By the help of this classification similar conditions can be fulfilled as it is guaranteed in the case of randomized controlled trials, namely the population within propensity-subgroups can be considered close to identical, see [1]. If there is sufficient information available about the patients, causal relationships can also be studied. A real life example of using propensity scores is a comparison study, which proposes to compare therapies on the schizophrenic patients in Hungary, see [2].

The abovementioned method is shown in a simulation study comparing the effect of two therapies (*A* and *B*) on mortality. In Figure 1 the survival functions of therapy *A* and *B* are shown, where the blue/red lines represent the raw/propensity adjusted model. Important to note, that the survival function of the raw model represents the overall population, while in the adjusted case there are different survival functions applied in all propensity-subgroups. Although the survival functions can vary by propensity-subgroups, the relative risk (RR) between the therapies is constant in all sub-groups. The results of the model estimations are summarized in Table 1. The relative risks (therapy *B* vs. therapy *A*) are presented in the second column for both the raw and the adjusted model. In the raw model the relative risk of mortality is below 1, RR=0.71 (95%CI: 0.55-0.86), hence the effect of therapy *B* is significantly better. This is shown in Figure 1, where the blue dashed line (therapy *B*) is over the blue solid line (therapy *A*). It turns out from the propensity adjusted model, that the results of the raw model are caused by inhomogeneity within the population, and after homogenization the RR of the mortality is over 1, RR=1.39 (95%CI: 1.11-1.66). **The relative risks and the survival lines clearly show that the propensity adjusted model can even lead to the opposite conclusion as one gets from the raw model.**

Table 1.: Comparison of therapy *A* and *B*

Model	Relative risk, therapy *B* relative to *A* (RR)	Standard error	p-value
Raw	0.71	0.08	0.01
Adjusted (*)	1.39	0.14	0.02

Figure 1: Survival curves



[1] Rosenbaum, P. R. and Rubin, D. B. (1983) The central role of the propensity score in observational studies for causal effects, Biometrika, 70, 41-55.
[2] Bitter, I., Katona, L., Zámbori, J., Takács, P., Fehér, L., Diels, J., Bacskai, M., Lang, Zs., Gyáni, G. and Czobor, P. (2013) Comparative effectiveness of depot and oral second generation antipsychotic drugs in schizophrenia: A nationwide study in Hungary, European Neuropsychopharmacology
http://www.healthware.hu/files/public/EUNEU_Comparative_effectiveness_of_depot_and_oral_aps.pdf

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