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Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE CONSULTING LTD.

News, current issues

- **Legislations** come into force between 01/06/2015 and 01/07/2015**:** Act XI of 1991 (01.07.2015); Act LXXXIII of 1997 (30.06.2015,01.07.2015); Act CLIV of 1997 (01.07.2015); Act XXV of 1998 (01.07.2015); Act XCV of 2005 (01.07.2015); Act XCVII of 2006 (01.07.2015); Act XCVIII of 2006 (01.07.2015); NM Decree No.9/1993. (13.06.2015); Gov.Decree No.43/1999. (01.06.2015); Gov.Decree No.323/2010. (01.06.2015); ESzCsM Decree No.32/2004. (13.06.2015)
- **NEWS** [HUN: *"Changes in (pharmaceutical) procurement - could be more than one winner?"* link
- **NEWS** [HUN]: *"Billions for unique support will be given to a drug company"* link
- **NEWS** [HUN]: *"New rules for reimbursement decisions are being made"* link
- **NEWS** [HUN]: *"A new "first drug" in the European Union"* link
- **NEWS** [HUN]: *"The new Law on healthcare was accepted"* link
- **NEWS:** *"Slow growth in health spending but Europe lags behind"* link
- **STUDY** [HUN]**:** *"How much? …150! What is 150? …How much what?"* link

Legislation follow-up

In recent years, the Hungarian pharmaceutical market is characterized by an increased constant change and multiplication of the regulators, and more dense interval transformation of the system's formed elements. In the case of the change in the examined legal environment the previous and the current contexts are presented expressively, so you can be rapidly informed about the legal changes.

Downloadable document: Legislation follow-up (sample)

More 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	2014. I-XII.	2015 original appropriation	2015		
			I-V. months	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 907,1**	**1 910,8**	**769,9**	**96,7%**	**100,1%**
Curative preventive provisions	945,6	948,6	389,2	98,5%	103,7%
Medicine subsidies	302,3	298,1	131,4	105,8%	105,8%
Medicine subsidies (pharmacy)	286,4	224,4	126,8	135,6%	107,5%
Total of Budgetary Revenues	**1 907,1**	**1 910,8**	**807,7**	**101,4%**	**99,4%**
Social Security Contributions	896,3	1 198,5	509,1	102,0%	134,5%
Contribution of Pharmaceutical Manufacturers and Wholesalers	57,4	58,0	28,3	117,1%	112,0%
Balance	**0,0**	**0,0**	**37,9**		**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 five months of 2015 the Health Security Fund produced a 4,76% surplus mainly because of the higher social security contributions (+2%) and the lower curative preventive provisions (-2,5%). Medicine subsidies shows 5,8% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission.

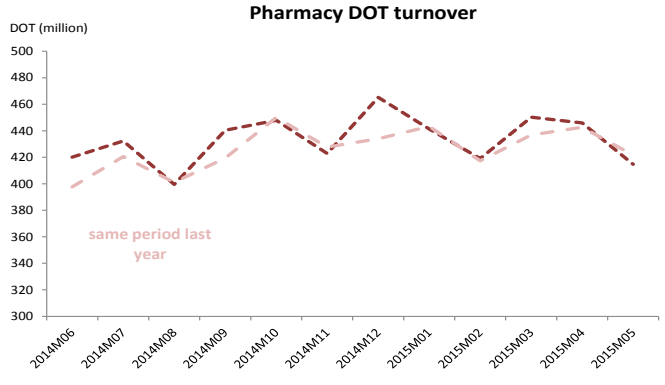
Changes to subsidised medicinal product categories

Changes in the public drug list	2015 Feb.	2015 Mar.	2015 Apr.	2015 May	2015 June	2015 July	2015
Number of new products	6	31	57	11	16	12	159
Number of new AI	2	5	2	1	2	2	17
Number of delisted products	10	36	44	51	30	16	213
Prices							
Decrease	1	7	166	3	0	42	243
Increase	0	0	3	0	0	5	11

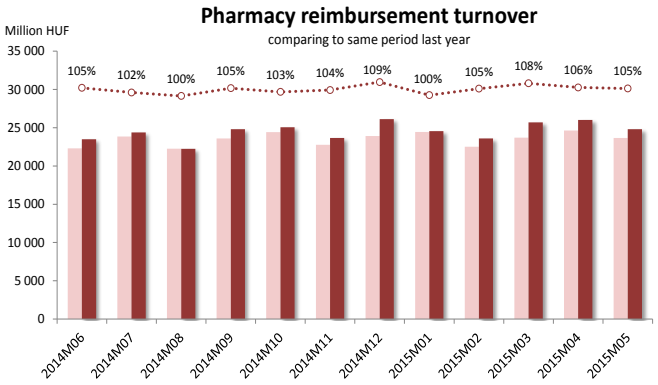
Changes in the public drug list	2015 Feb.	2015 Mar.	2015 Apr.	2015 May	2015 June	2015 July	2015
Reimbursement							
Decrease	1	6	393	1	0	71	519
Increase	0	1	69	0	0	6	89
Co-payment							
Decrease	1	14	255	5	0	47	364
Increase	0	1	280	0	0	34	339

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 five months of 2015 was 0,57% higher than the same period last year, while the average reimbursement per DOT increased with 2,54% compared to the previous month and was higher with 7,56% than tha last year's average. The reimbursement turnover is 4,15% higher for this period compared to last year.

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Market data

Marketing authorisation information

2014	EMA	OGYI
New brands	70	182
New SKUs	359	1 879

2015 - Q1	EMA	OGYI
New brands	25	42
New SKUs	143	532

May 2015	EMA	OGYI
New brands	6	10
New SKUs	71	73

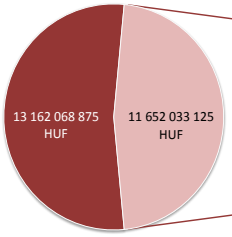
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 05/2015

All	1 837
Medicinal products	1 556
Medical aids	252
Both	29

Source: Healthware analysis based on OGYI's

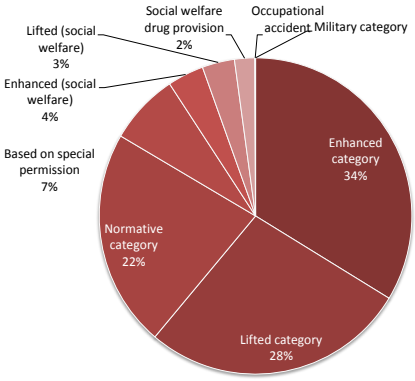
TOP10 DISTRIBUTOR by all reimbursement paid in May 2015



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 253 280 756 HUF
SANOFI-AVENTIS Zrt.	1 537 464 409 HUF
EGIS Gyógyszergyár Zrt.	1 220 892 466 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 161 146 192 HUF
TEVA Gyógyszergyár Zrt.	1 122 369 336 HUF
Pfizer Kft.	981 545 738 HUF
Lilly Hungaria Kft.	905 488 950 HUF
Novo Nordisk Hungária Kft.	887 160 116 HUF
Sandoz Hungária Kereskedelmi Kft.	806 103 398 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	776 581 762 HUF

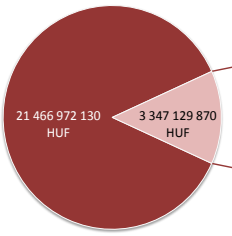
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 05/2015



Source: Healthware analysis based on the sales

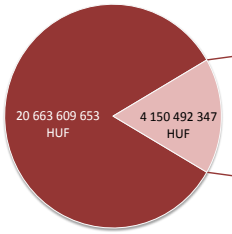
TOP10 BRAND by all reimbursement paid in May 2015



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	513 727 928 HUF
GLIVEC	Novartis Hungária Kft.	504 373 134 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing S	380 541 610 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H	378 060 797 HUF
LANTUS	SANOFI-AVENTIS Zrt.	326 052 944 HUF
HUMULIN	Lilly Hungaria Kft.	281 720 380 HUF
SUTENT	Pfizer Kft.	266 704 633 HUF
TASIGNA	Novartis Hungária Kft.	236 774 740 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	235 213 535 HUF
COVEREX	EGIS Gyógyszergyár Zrt.	223 960 171 HUF

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

TOP10 ATC by all reimbursement paid in May 2015



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	513 727 928 HUF
L01XE01	imatinib	504 373 134 HUF
V06D	other nutrients	481 438 393 HUF
J05AX67	ombitasvir, paritaprevir and ritonavir	472 642 112 HUF
N05AX13	paliperidone	451 082 314 HUF
C10AA07	rosuvastatin	386 454 035 HUF
R03BB04	tiotropium bromide	378 060 797 HUF
A10AB01	insulin (human)	339 178 180 HUF
A10AE04	insulin glargine	326 052 944 HUF
C09BA04	perindopril and diuretics	297 482 510 HUF

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

TOP10 ATC by number of patients in May 2015

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetilszalicilsav	340 731
C09BA04	perindopril és vizelethajtók	281 218
C08CA01	amlodipin	266 216
C07AB12	nebivolol	236 232
C10AA05	atorvastatin	231 626
C10AA07	rosuvastatin	210 696
A02BC02	pantoprazol	193 628
M04AA01	allopurinol	193 389
C09AA04	perindopril	172 225
C09BB04	perindopril és amlodipin	162 307

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

Health State Valuation in Children — Case study

When evaluating drugs for reimbursement it is commonly expected that decision makers can rely on health-economic analyses about the cost-effectiveness of the particular therapy.

Based on guidelines from the Hungarian Ministry of Human Capacities, "utility values are recommended to be calculated based on questionnaires measuring health related quality of life and using preference-based utilities"[1].

In cases of young children, especially infants and pre-schoolers the use of quality of life questionnaires is highly impeded. Therefore the topic of our case study **in the July Newsletter is a review of the challenges of using preference-based measures of utility when evaluating health improvements in young children, and the currently available options to solve this problem.**

The base statement of the article is that there is no valid and reliable preference-based measure of utility for valuation of health states for children of all ages. (Ungar WJ)[2]

Direct methods of determining utility values presuppose a certain level of cognitive skills of the respondent. However, understanding the state and possibility of death or the concept of time, and articulation of preferences based on all these cannot be expected from children of young age. **Indirect methods** (eg. health quality questionnaires) require less advanced cognitive skills. These instruments however can be challenging to children because of their grammar and terminology. Children can express different preferences to certain health states than adults. Their sense of "normal" or any changes in their health state is strongly dependent on factors related to family and social functionality, furthermore their concept of health is continuously changing as they develop emotionally and physically.

A potential solution addressing the limitations of direct and indirect methods listed above is the Child Health Utility (CHU)-9D, an indirect measure that was exclusively developed by involving children. Although the description of health states reflect dimensions that are relevant to children, the associated utility weights are derived from the adult population's preferences. The instrument focuses on a current health state avoiding the distortions related to the inability of children recalling past events accurately, requiring a more frequent administration. The questionnaire can be applied in children between 7-11 years to determine health state utilities. Valid questionnaires used in different age groups are presented in the next figure.

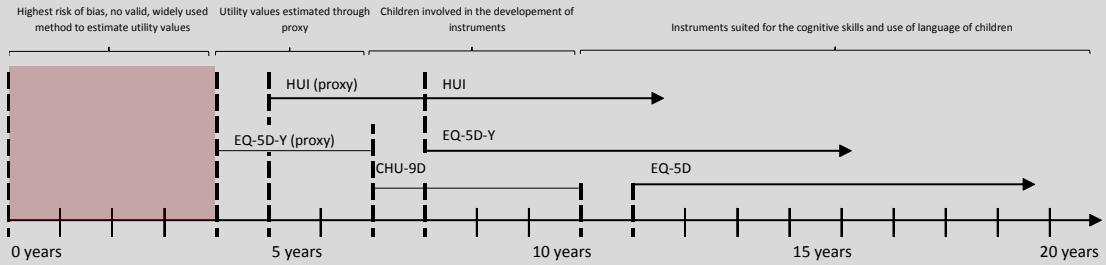
In cases of infants and pre-schoolers, neither direct nor indirect methods can be applied, so a proxy respondent (parent or caregiver) should be mediating. He or she should imagine how a certain health state is experienced by the child – weather or not the responder knows the child by person. According to other researchers utility values of children should not be examined solely in themselves, since the state of the child has a strong impact on the whole family.

Several endeavours aim to reduce the limitations of health state valuation in children. Nevertheless using new or old, direct or indirect instruments on children or proxy responders, the determined utilities should be applied with caution.

Cost-utility analyses can be implemented with limitations in cases of health technologies applied in early-childhood or related to mental conditions (psychiatric pathologies affecting the central nervous system, infant nutrition formulas, etc.). These technologies should be rather evaluated based on cost-minimization or cost-effectiveness analyses. In these cases, problems may emerge when new technologies are about to enter the market with premium prices. It may not be possible to assess the health gains and additional costs of these technologies objectively, based on standardized outputs – and as a result, these therapies experience drawbacks, merely because of their indications. Furthermore, the heterogeneous environment of cost-effectiveness indicators could prevent the applicability of official thresholds.

It would be crucial to elaborate resolutions regarding these issues, to clarify the principles of health policy and clinical practice based on which these technologies could be satisfactorily assessed.

1: Az Egészségügyi Minisztérium szakmai irányelve az egészség-gazdaságtani elemzések készítéséhez. 2013. Egészségügyi Közlöny. 11. szám 1314-1334.
2: Ungar WJ. Challenges in health state valuation in paediatric economic evaluation: are QALYs contraindicated? Pharmacoeconomics. 2011 Aug;29(8):641-52.



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