

Actualities of Hungarian pharmaceutical financing market

Newsletter



News, current issues

- **Legislations** come into force between 01/12/2016 and 01/01/2016: Act XI of 1991 (01.01.2016); 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); Act XCVII of 2006 (01.01.2016); Act XCVIII of 2006 (01.01.2016); 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.235/2009. (01.01.2016); 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:** "Drug budget is burst by Ratko children" [link](#)
- **NEWS:** "NH Service Center remains, NHIF will be reorganized" [link](#)
- **NEWS:** "Drug approvals at 19-year high belie industry challenges" [link](#)
- **NEWS:** "NHS: Current price volume agreements (PVA)" [link](#)
- **NEWS:** "Pharm. companies are facing billions expenditure" [link](#)
- **NEWS:** "Samsung Bioepis' Enbrel copy gets EU approval" [link](#)
- **NEWS:** "Cancer is the Hungarian disease" [link](#)

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Health Security Fund	2014. I-XII.	2015 original appropriation	2015		
			I-XI. months	% of appropriation	% of last year
Total of Budgetary Expenditures	1 907,1	1 910,8	1 760,8	100,5%	102,3%
Curative preventive provisions	945,6	948,6	856,8	98,5%	101,4%
Medicine subsidies	302,3	298,1	292,7	107,1%	106,1%
Medicine subsidies (pharmacy)	286,4	224,4	282,6	137,4%	107,6%
Total of Budgetary Revenues	1 907,1	1 910,8	1 756,5	100,3%	99,8%
Social Security Contributions	896,3	1 198,5	1 113,1	101,3%	140,1%
Contribution of Pharmaceutical Manufacturers and Wholesalers	57,4	58,0	59,4	111,7%	123,1%
Balance	0,0	0,0	-4,2		0,0%

Billion HUF

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 eleven months of 2015 the Health Security Fund produced a 0,24% deficit. Medicine subsidies shows 7,1% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission.

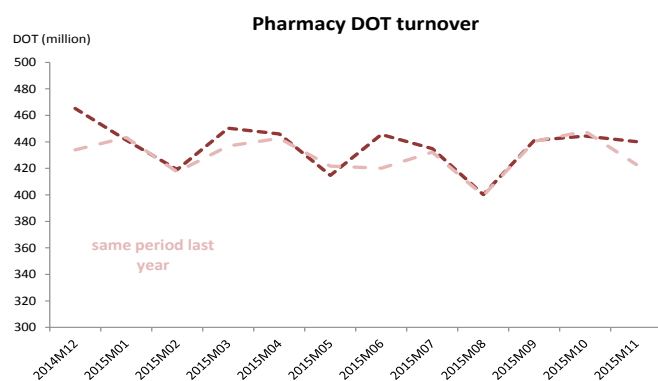
Changes to subsidised medicinal product categories

Changes in the public drug list	2015	2015	2015	2015	2015	2016	2016
	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	
Number of new products	34	22	34	23	8	28	28
Number of new AI	4	3	2	3	1	5	5
Number of delisted products	16	8	40	18	20	27	27
Prices							
Decrease	5	2	120	8	0	31	31
Increase	0	0	0	0	0	0	0

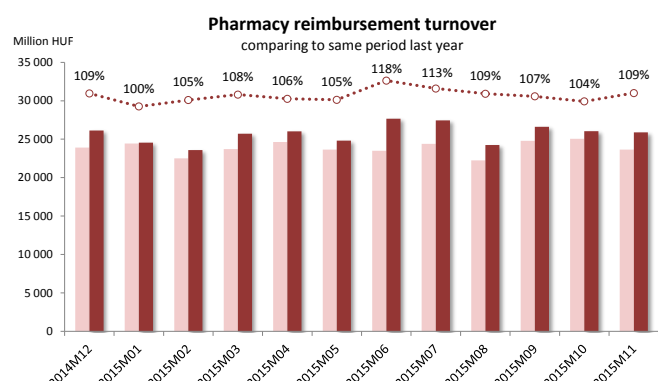
Changes in the public drug list	2015	2015	2015	2015	2015	2016	2016
	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	
Reimbursement							
Decrease	1	1	389	5	0	40	40
Increase	0	0	56	0	0	24	24
Co-payment							
Decrease	2	2	171	12	0	67	67
Increase	1	1	313	0	0	16	16

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

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 eleven months of 2015 was 0,96% higher than the same period last year, while the average reimbursement per DOT increased with 0,39% compared to the previous month and was higher with 5,75% than the last year's average. The reimbursement turnover is 6,83% higher for this period compared to last year.

Survey of references, meta – analysis

We collect the available information, evidence in related articles, directives, studies, research. As the first step of systematic research of the scientific literature we define the relevant keywords. Then we present the evidence charts, it is followed by organization and comparative analysis.

Meta – analysis

We are able to make an exact summary of the results with statistical methods, which is based on the systematic research of scientific literature that led to compiling the parameters of evidence charts.

More details: [link](#)

Product offering



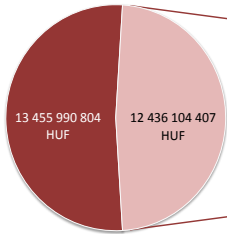
Market data

Marketing authorisation information

2014	EMA	OGYI	2015 - Q3	EMA	OGYI	November 2015	EMA	OGYI
New brands	70	182	New brands	26	57	New brands	19	14
New SKUs	359	1 883	New SKUs	310	604	New SKUs	126	247

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

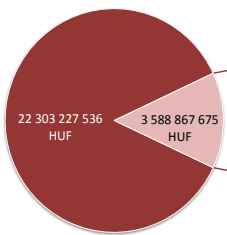
TOP10 DISTRIBUTOR by all reimbursement paid in November 2015



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 423 809 878 HUF
SANOFI-AVENTIS Zrt.	1 635 904 170 HUF
EGIS Gyógyszergyár Zrt.	1 296 064 000 HUF
Richter Gedeon Vegészeti Gyár NyRt.	1 248 833 119 HUF
TEVA Gyógyszergyár Zrt.	1 191 693 280 HUF
Pfizer Kft.	1 137 526 406 HUF
Novo Nordisk Hungária Kft.	952 332 031 HUF
Lilly Hungaria Kft.	914 830 795 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	843 838 126 HUF
Sandoz Hungária Kereskedelmi Kft.	791 272 603 HUF

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

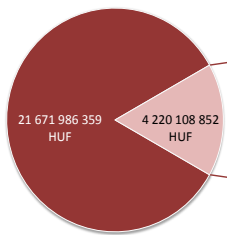
TOP10 BRAND by all reimbursement paid in November 2015



TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	541 368 128 HUF
CLEXANE	SANOFI-AVENTIS Zrt.	535 709 922 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing S	444 370 351 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H	370 538 503 HUF
LANTUS	SANOFI-AVENTIS Zrt.	347 356 558 HUF
HUMULIN	Lilly Hungaria Kft.	291 550 305 HUF
SUTENT	Pfizer Kft.	284 422 742 HUF
TASIGNA	Novartis Hungária Kft.	261 640 354 HUF
TECFIDERA	Biogen Idec Hungary Kft.	258 127 247 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	253 783 566 HUF

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

TOP10 ATC by all reimbursement paid in November 2015



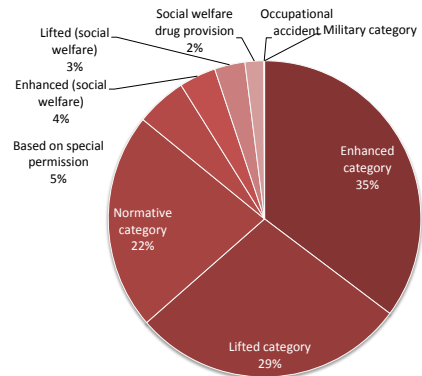
TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
L01XE01	imatinib	541 368 128 HUF
V06D	other nutrients	538 191 401 HUF
B01AB05	enoxaparin	535 709 922 HUF
N05AX13	paliperidone	515 520 289 HUF
C10AA07	rosuvastatin	421 801 427 HUF
R03BB04	tiotropium bromide	370 538 503 HUF
A10AE04	insulin glargine	353 209 110 HUF
A10AB01	insulin (human)	349 142 417 HUF
C09BA04	perindopril and diuretics	310 204 914 HUF
L01XE04	sunitinib	284 422 742 HUF

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

Average number of medical sales reps; 11/2015

All	1 810
Medicinal products	1 552
Medical aids	234
Both	25

Drug reimbursement by legal title; 11/2015



Source: Healthware analysis based on the sales

TOP10 ATC by number of patients in November 2015

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	351 212
C09BA04	perindopril and diuretics	287 810
C08CA01	amlodipine	264 345
C07AB12	nebulivolol	244 301
C10AA05	atorvastatin	232 338
C10AA07	rosuvastatin	224 490
A02BC02	pantoprazole	215 634
M04AA01	allopurinol	205 927
A11CC05	coleciferol	197 385
C09AA04	perindopril	176 995

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

Defining the length of the therapy – questions of the methodology and importance in the research – Case study

Almost every case, the main topic of the retrospective, real-world data based pharmaceutical research are the examination of the medication, but usually we don't have real information about the medication of every patient in the real life. However, what we have just the date of the drug filling or the date of the prescription and a definition (from different source) about the daily dose of the medicine. Based on the daily dose we can create a lot of derived indicator (connected to an active substance or specific product): e.g. daily cost of therapy, duration of the therapy, co-medication, adherence, persistence, PFS, or the definition of dominant therapy during a period.

Basically, the length of the therapy means that how many days are covered the pills in a unit, its measure is the DOT. The National Health Insurance Fund in Hungary also uses this measure in the public drug list (PUPHA). It's a derived indicator, from this formula:

DOT= all active substance content of a unit/ DDD(Defined Daily Dose)

Originally the DOT was created to make comparable the different measures of various dosage forms e.g. gram, milligram, milliliter, international unit etc.). The main parameter in the formula is the DDD value, the origin of the different DOT values is the consequence of DDD's different approaches. DDD is the well-known abbreviation of the "Defined Daily Dose" expression, the recommended daily dose of the different products. In the field of Hungarian pharmaceutical research 5 different DOT estimations are being used, with different accuracy and time consuming.

1. OEP/NHIFA DOT or PUPHA DOT: it comes from the National Health Insurance Fund's monthly drug list, based on the WHO DDD value, but not in every case.

2. Adjusted OEP/NHIFA DOT: the OEP value adjusted with the WHO DDD. The WHO DDD value is based on the following principles: DDDs for single substances are normally based on monotherapy, DDD will normally not be assigned for a substance before product is approved and marketed in at least one country. For substances indicated for rare disorders with individual dosing, the Working Group could decide not to assign a DDD. It's important to notice, that when the recommended dose refers to body weight, an adult is considered to be a person of 70 kg, and the DDD will usually be the average of the maintenance dose range in the main indication. The DDD is often identical for various dosage forms of the same drug. Different DDDs could be available when the bioavailability is radically different for various routes of administration.

A WHO Collaborating Centre for Drug Statistics Methodology yearly publishes the Guidelines for ATC classification and DDD assignment. The latest version was published in January 2016 and available [here](#).

3. Estimation based on the Summary of Product Characteristics – In Hungary the **OGYEI** (National Institute of Pharmacy and Nutrition), in Europe, the **EMA** is responsible for publishing the Summary of Product Characteristics with the recommended dosage specification. This documents contains the different recommended dose in the different indications, or during titrate period versus maintenance therapy. The DDD value in this documents could be vary from the WHO DDD.

4. OEP/NHIFA estimated DOT value – it's also published by the OEP, in the turnover report, it's based on the filling data from the last 12 months.

5. A patient subgroup (connected to a product) DOT value. Based on real DDD's, from real world filling data (mean and median value) at patient level.

For the Insurance Fund the DDD value is major phenomenon in the field of calculation considering positive reimbursement decisions and generic market access, and the FX process (internal reference pricing). Our example shows three products, where the PUPHA (NHIFA) DOT are barely different from the Summary of Product Characteristics value and from the patterns calculated on real world data. The NHIFA revised the products' DOT value through the review process, so the Daily Therapy Cost has changed significantly.

Product-packaging	Original NHIFA DOT value	Revised NHIFA DOT value	Mean DOT value (real world data)	Median DOT value (real world data)	SPC's DOT	Revise date	Original Daily Therapy Cost	Revised Daily Therapy Cost
Leuporelin 7,5 mg; 1x	55,97	28	30,38	29	30	2015.10.01	496 Ft	992 Ft
Leuporelin 22,5 mg; 1x	83,96	167,91	88,8	90	90	2011.07.01	992 Ft	496 Ft
Leuporelin 45 mg; 1x	335,82	167,97	171,43	175	180	2015.10.01	491 Ft	982 Ft

If the product was in a reimbursement FX group the revise of the Daily Cost of the Therapy may change the position of the product in the price competition and it could influence the status of the reference product and the reference price. It could also change the reimbursement and indirectly the amount of manufacturer's payback. From the information of the method of drug filling we can only conclude information about the real world drug consumptions, that's why the adequate definition of the length of the therapy is so important. If we use the proper indicator we have a good chance to estimate the length of the therapy of a specific patient group, it's essential not just the term for pharmaceutical researches but for the whole reimbursement system.