

Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE
CONSULTING LTD.

News, current issues

- **Legislations** come into force from June 2014: There was no change.
- **NEWS:** "Now you can learn how much the TB spent on you" [link](#)
- **NEWS:** "Pharma industry: the tax authority to investigate subsidies" [link](#)
- **NEWS:** "Money promised to hospitals" [link](#)
- **NEWS:** "Finally gratuities can disappear from Hungary" [link](#)
- **NEWS:** "U.S. FDA proposes social media guidelines for drug industry" [link](#)
- **STUDY:** "Eurobarometer - Patient safety and quality of care" [link](#)

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-V.	% of appropriation	% of last year
Total of Budgetary Expenditures	1 847,8	1 884,2	769,0	97,9%	105,4%
Curative preventive provisions	908,0	931,9	375,5	96,7%	110,8%
Medicine subsidies	296,0	294,1	124,2	101,4%	102,2%
Medicine subsidies (pharmacy)	281,5	222,4	118,0	127,3%	100,4%
Total Of Budgetary Revenues	1 847,8	1 884,2	812,5	103,5%	104,1%
Social Security Contributions	768,0	852,9	378,4	106,5%	118,4%
Contribution of Pharmaceutical Manufacturers and Wholesalers	58,7	56,0	25,3	108,3%	88,7%
Balance	0,0	0,0	43,6		85,7%

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 five months of 2014 the Health Security Fund produced a 5,55% surplus mainly because of the higher social security contributions (+6,5%) and lower spending. The in- and outcare expenditure was 3,3% lower than the budget plan proportional to that time interval.

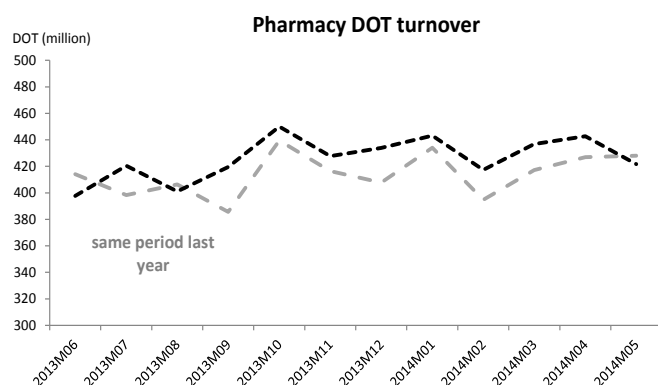
Changes to subsidised medicinal product categories

	Changes in the public drug list						
	2014 Feb.	2014 Mar.	2014 Apr.	2014 May	2014 June	2014 July	2014
Number of new products	34	13	16	21	22	18	146
Number of new AI	8	1	0	1	1	4	16
Number of delisted products	21	42	49	18	18	29	240
Prices							
Decrease	7	5	349	6	4	46	450
Increase	0	1	51	1	0	0	53

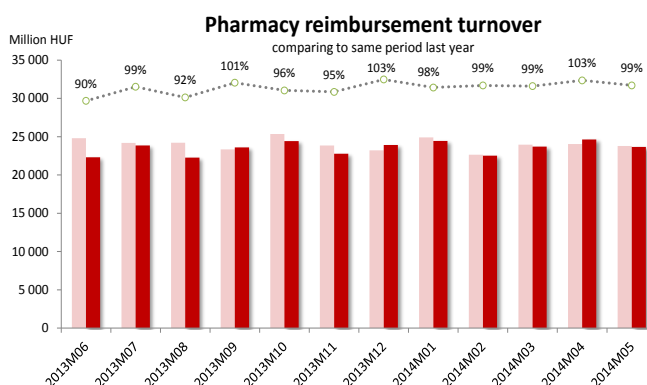
	Changes in the public drug list						
	2014 Feb.	2014 Mar.	2014 Apr.	2014 May	2014 June	2014 July	2014
Reimbursement							
Decrease	1	7	863	9	3	87	1 017
Increase	2	0	213	1	1	2	222
Co-payment							
Decrease	10	8	540	8	6	61	679
Increase	0	3	642	11	0	41	713

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 five months of 2014 was 2,89% higher than the same period last year, while the average reimbursement per DOT increased slightly compared to the previous month. The reimbursement turnover is 0,32% below for this period compared to last year.

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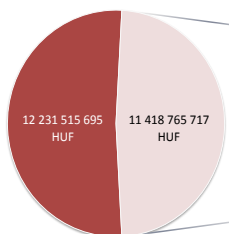
Market data

Marketing authorisation information

2013	EMA	OGYI	2014 - Q1	EMA	OGYI	May 2014	EMA	OGYI
New brands	79	207	New brands	16	56	New brands	8	13
New SKUs	716	1 742	New SKUs	185	510	New SKUs	55	96

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

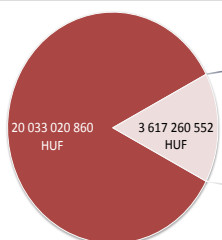
TOP10 DISTRIBUTOR by all reimbursement paid in May 2014



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 138 741 287 HUF
SANOFI-AVENTIS Zrt.	1 459 556 087 HUF
EGIS Gyógyszergyár Nyrt.	1 184 608 839 HUF
TEVA Gyógyszergyár Zrt.	1 166 881 501 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 107 582 529 HUF
Pfizer Kft.	993 128 481 HUF
Lilly Hungaria Kft.	911 636 739 HUF
Novo Nordisk Hungária Kft.	869 146 349 HUF
GlaxoSmithKline Kft.	803 088 388 HUF
Janssen-Cilag, Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	784 395 519 HUF

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

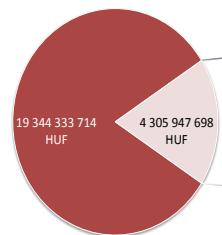
TOP10 BRAND by all reimbursement paid in May 2014



TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	543 330 154 HUF
CLEXANE	SANOFI-AVENTIS Zrt.	481 958 003 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H. N	426 806 502 HUF
SYMBICORT	Astra Zeneca AB	411 416 141 HUF
XEPLION	Janssen-Cilag, Gyógyszerkereskedelmi Marketing Sz	338 949 986 HUF
LANTUS	SANOFI-AVENTIS Zrt.	317 619 913 HUF
SERETIDE	GlaxoSmithKline Kft.	308 858 552 HUF
HUMULIN	Lilly Hungaria Kft.	286 095 632 HUF
SUTENT	Pfizer Kft.	264 945 266 HUF
RISPERDAL	Janssen-Cilag, Gyógyszerkereskedelmi Marketing Sz	237 280 403 HUF

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

TOP10 ATC by all reimbursement paid in May 2014



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
R03AK07	formoterol and other drugs for obs. airway diseases	606 270 305 HUF
L01XE01	imatinib	543 330 154 HUF
B01AB05	enoxaparin	481 958 003 HUF
V06D	other nutrients	428 345 201 HUF
R03BB04	tiotropium bromide	426 806 502 HUF
N05AX13	paliperidone	417 535 442 HUF
R03AK06	salmeterol and other drugs for obs. airway diseases	371 284 615 HUF
C10AA07	rosuvastatin	364 360 862 HUF
A10AB01	insulin (human)	348 436 701 HUF
A10AE04	insulin glargine	317 619 913 HUF

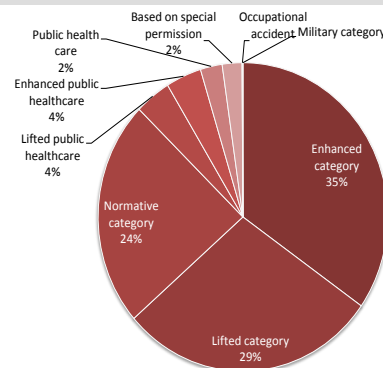
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Average number of medical sales reps; 05/2014

All	1 801
Medicinal products	1 541
Medical aids	219
Both	41

Source: Healthware analysis based on OGYI's

Drug reimbursement by legal title; 05/2014



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

Investigation of pharma payback and clawback policies in Europe — Case

The extensive growth of public spending on pharmaceuticals has led to the introduction of various kind of cost containment policies in the European countries in the past decade. Wide range of different mechanisms can have been discovered in the health financing systems which aim to control the extent of drug spending on a product, therapy or global level. However as a consequence of the financial crisis there is a bigger burden on the national budgets thus more and more new and country specific measures were introduced lately. While many kind of sophisticated methods are available with which it is possible to reduce the expenditure without threatening the quality and safety of care, the set of a simple budget cap and the payback or clawback policies appeared in several EU countries' legislation.

Our aim was to find out those EU countries that apply some kind of payback or clawback policies which mean that pharmaceutical companies have to pay back a certain part of the public reimbursement. It gives an additional importance to this issue that for international comparison analysis of drug spending the often used OECD or EUSTAT databases are distorted in case they do not include these amounts.

We found 12 countries that apply payback or clawback measures: Belgium, Latvia, Hungary, France, Portugal, Romania, Greece, Italy, Poland, Slovenia, and United Kingdom. We details the rules of six of them:

France¹

Three kinds of payback systems which ordain 50-70% of the overspending:
Aggregate level: Proportionate repayment above the level of the pre-set yearly growth by therapeutic groups.
Producer level: Repayment over the exceeding of the turnover by producers
Product level: Independently of the national turnover, repayment on the basis of average cost and doses.
In 2010 the French drug agency had 90 million euro revenue from repayment by pharmaceutical companies.

Italy²

Repayment above the determined regional budget caps. It can be avoided by a 5% general price cut to the product portfolio.
In 2012 the pharmaceutical companies repaid a total amount of 113 million euro.

UK³

The system introduced in 2014 orders a full repay over a pre-set target spending, in the framework of a voluntary agreement between the financier and the companies.
In the first quarter of 2014 the repayment was 4% of the total drug turnover.

Romania⁴

From 2012 there is clawback system which ordain the quarterly repayment in case the spending is above a pre-set level.
In 2011 the repayment reached one third of the total turnover.

Poland⁵

In 2011 a new rule was introduced according which, in case the drug spending goes over 17% of the total health spending, half of the overspending has to be paid back by the drug companies. Since then they haven't had to apply this rule.

Hungary⁶

Since 2006 a monthly 20% repayment based on the monthly turnover, with an additional 10% for special therapies, and a clawback after budget overspending.
In 2013 these special taxes on pharmaceutical companies amounted to 16% of the total drug turnover.

1. Rapport à la Commission des comptes de la Sécurité sociale

2. Italian Medicines Agency

3. Association of the British Pharmaceutical Industry (ABPI)

4. Doina Margaritti, Angela-Eliza Micu: Considerations regarding the influence of the Clawback Tax in the development of the Romanian pharmaceutical industry, 2012

5. Narodowym Funduszem Zdrowia

6. National Health Insurance Fund Administration