



News, current issues

- **Legislations** come into force from October 2014: NM Decree No.9/1993. (2014.10.01.)
- **NEWS:** "Innovative manufacturers initiate negotiations" [link](#)
- **NEWS:** "More frequent data updates to promote patient safety" [link](#)
- **NEWS:** "The government has accepted new plans for restructuring the health system" [link](#)
- **NEWS:** "Dividing health care - what do insurers think?" [link](#)
- **NEWS:** "Setting up the new public health organization system is expected to finish by next spring" [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-IX. months	% of appropriation	% of last year
Total of Budgetary Expenditures	1 847,8	1 884,2	1 413,7	100,0%	105,8%
Curative preventive provisions	908,0	931,9	699,3	100,1%	110,0%
Medicine subsidies	296,0	294,1	223,8	101,4%	102,4%
Medicine subsidies (pharmacy)	281,5	222,4	213,1	127,8%	101,7%
Total of Budgetary Revenues	1 847,8	1 884,2	1 442,3	102,1%	103,7%
Social Security Contributions	768,0	852,9	670,9	104,9%	117,2%
Contribution of Pharmaceutical Manufacturers and Wholesalers	58,7	56,0	43,6	103,8%	93,8%
Balance	0,0	0,0	28,6		52,4%

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 nine months of 2014 the Health Security Fund produced a 2,02% surplus mainly because of the higher social security contributions (+4,9%).

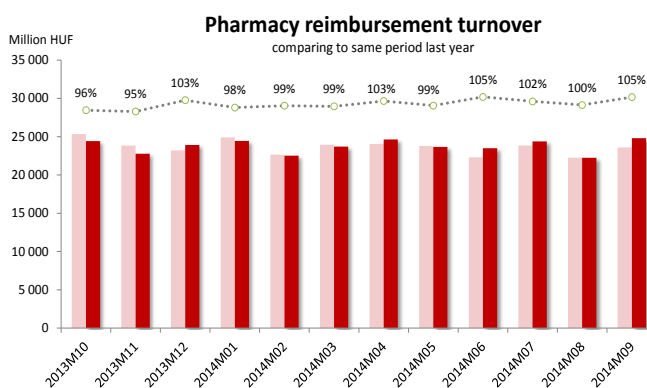
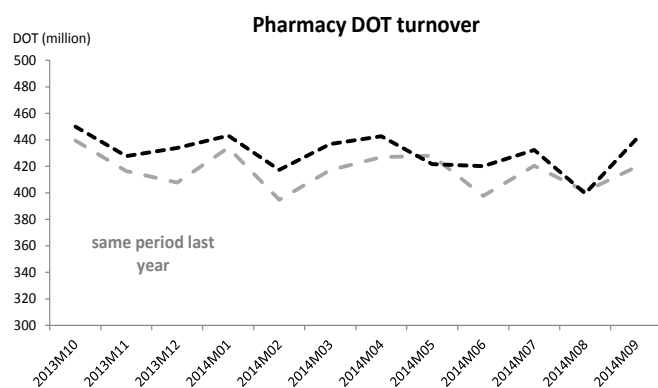
Changes to subsidised medicinal product categories

	Changes in the public drug list							2014
	2014 June	2014 July	2014 Aug.	2014 Sep.	2014 Oct.	2014 Nov.	2014	
Number of new products	22	18	21	26	23	13	229	
Number of new AI	1	4	3	1	1	1	22	
Number of delisted products	18	29	26	20	47	23	356	
Prices								
Decrease	4	46	10	7	263	3	733	
Increase	0	0	1	2	2	0	58	

	Changes in the public drug list							2014
	2014 June	2014 July	2014 Aug.	2014 Sep.	2014 Oct.	2014 Nov.	2014	
Reimbursement								
Decrease	3	87	11	2	683	1	1 714	
Increase	1	2	2	0	78	1	303	
Co-payment								
Decrease	6	61	18	9	348	7	1 061	
Increase	0	41	2	2	511	0	1 228	

Source: Healthware analysis based on OEP-PUPHA data

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



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 nine months of 2014 was 3,05% higher than the same period last year, while the average reimbursement per DOT increased slightly compared to the previous month. The reimbursement turnover is 1,19% higher for this period compared to last year.

Questionnaire survey

Many marketing and health economic analyzes require information beyond the data in literary publications, that correct and complete them. In our projects the more frequently planned longitudinal data collection, fact finding and new information generating researches could provide useful support in addition to ad hoc surveys. Main steps:

- Preliminary review and interpretation of the input parameters
- Establishment of questionnaire involving 1-2 local experts
- Finalization of the questionnaires and querying on larger sample
- Receiving replies, recording questionnaires, processing responses, statistical evaluation
- Validation of results with the help of a local expert
- Web Report transfer in Hungarian and English language

Downloadable document: [Cost-minimisation analysis of aripiprazole \(Abilify®\) for the treatment of acute bipolar disorder in Hungary](#)

More about the service: [link](#)

Product offering



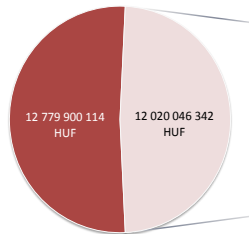
Market data

Marketing authorisation information

2013	EMA	OGYI	2014 - Q3	EMA	OGYI	September 2014	EMA	OGYI
New brands	80	207	New brands	13	33	New brands	6	1
New SKUs	719	1 768	New SKUs	113	281	New SKUs	50	2

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

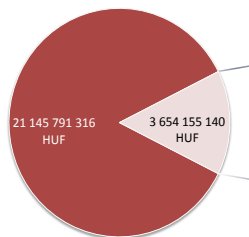
TOP10 DISTRIBUTOR by all reimbursement paid in September 2014



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 260 457 387 HUF
SANOPI-AVENTIS Zrt.	1 552 023 487 HUF
TEVA Gyógyszergyár Zrt.	1 252 491 814 HUF
EGIS Gyógyszergyár Zrt.	1 251 889 817 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 194 646 154 HUF
Pfizer Kft.	1 029 394 103 HUF
Lilly Hungaria Kft.	936 296 167 HUF
Novo Nordisk Hungária Kft.	887 198 014 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	852 651 302 HUF
Sandoz Hungária Kereskedelmi Kft.	802 998 098 HUF

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

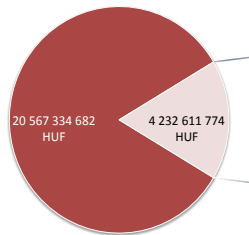
TOP10 BRAND by all reimbursement paid in September 2014



TOP 10 - BRAND	Distributor	Reimbursement
GLIVEC	Novartis Hungária Kft.	566 046 724 HUF
CLEXANE	SANOPI-AVENTIS Zrt.	511 345 525 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H. N	419 696 825 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Marketing Sz	388 562 341 HUF
SYMBICORT	Astra Zeneca AB	387 356 839 HUF
LANTUS	SANOPI-AVENTIS Zrt.	335 012 167 HUF
HUMULIN	Lilly Hungaria Kft.	295 681 580 HUF
SUTENT	Pfizer Kft.	271 003 815 HUF
LEVEMIR	Novo Nordisk Hungária Kft.	240 310 135 HUF
RISPERDAL	Janssen-Cilag Gyógyszerkereskedelmi Marketing Sz	239 139 189 HUF

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

TOP10 ATC by all reimbursement paid in September 2014



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
L01XE01	imatinib	566 046 724 HUF
B01AB05	enoxaparin	511 345 525 HUF
N05AX13	paliperidone	468 041 527 HUF
V06D	other nutrients	460 864 361 HUF
R03AK07	formoterol and other drugs for obs. airway diseases	428 679 412 HUF
R03BB04	tiotropium bromide	419 696 825 HUF
C10AA07	rosuvastatin	380 474 177 HUF
A10AB01	insulin (human)	360 612 133 HUF
A10AE04	insulin glargine	335 012 167 HUF
C10AA05	atorvastatin	301 838 924 HUF

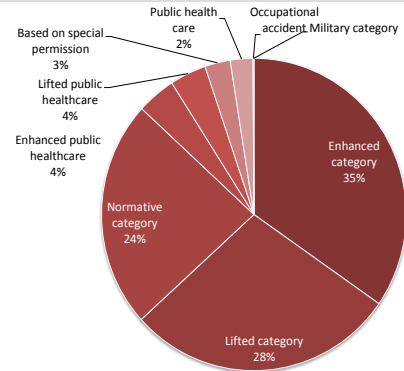
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Average number of medical sales reps; 09/2014

All	1 708
Medical products	1 453
Medical aids	232
Both	23

Source: Healthware analysis based on OGYI's

Drug reimbursement by legal title; 09/2014



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

Financing scheme of high value, not reimbursed oncological therapies in England — Case study

In our current case study we present an example for the financing scheme of high value oncological therapies. In England a so called Cancer Drugs Fund (CDF) ([link](#)) was grounded temporarily in the frame of a program aimed at restructuring the pricing of the oncological products. The goal of the Fund was making such oncological products available to the patients, which haven't been assessed in reimbursement perspective yet or which were not considered effective or cost effective by the NICE.

The Fund will be operating for 5 years from April 2011 to March 2016, and it will be supervised by NHS England. The Cancer Drugs Fund currently works with a budget of £280 million, in addition to the £1.3 billion budget for cancer drugs routinely available to the patients. The Fund makes drugs available in two ways:

National priority list: The priority list prescribes the cancer types and the circumstances which the given drug should be applied on ([link](#)). The application is submitted by the medical specialists of the patients to the regional authorized panels of the Cancer Drugs Fund, which makes the decision in a couple days. The drugs that CDF covers change as new drugs become available or if NICE makes a decision making the drug routinely available within the NHS. Last year (2013.04-2014.03) 56 application was submitted to the Fund, from which 14 were granted full (see the table) and 10 were granted limited approval. Currently 42 active ingredients are on the list in 73 different indication.

Individual application: The Fund will also consider applications on behalf of individual patients for other drugs that are not on the list. This is usually to treat rare cancers. CDF panels usually respond within 10 days.

In Hungary uncovered products are available in normal financing procedure by individual compassionate application (not only in oncology). The applications should be submitted by the patient along with the required documentation, and it is judged individually. The decision making body is the National Health Insurance Fund (OEP), the decision process is 30 days, or 12 days for off label use. In life-saving or life-threatening cases the judging is out of turn, but documents are still needed ([link](#)).

In connection with the CDF, critical comments were appeared based on last year's experiences, which questioned the compassionate function and the effectiveness of the Fund. The critics focus on the fact that only four drugs – bevacizumab, abiraterone, bendamustine and cetuximab – account for nearly 53 per cent of all patient notifications (requests) to the CDF and nearly half of all patient notifications to the fund are for drugs supplied by three manufacturers: Roche, Janssen and Novartis.

In spite of this priority list can be appropriate and in verifiable circumstances, an example to follow for the products under individual request. It can help the patients to access to the suitable drugs easier and faster, and it can support the new, unknown products getting under coverage.

New full approvals (04.2013.-03.2014.)

INN	CDF indication	Availability in Hungary
afibercept	CRC	the reimbursement submission was ceased in 2013, it hasn't got turnover in compassionate use
bevacizumab	1L CRC	reimbursed under itemized accounting in first, second and third line treatment of unresectable metastatic colorectal carcinoma in KRAS wild type
bevacizumab	ovarian	its usage was allowed several times by National Institute of Pharmacy (NIP)*, it has turnover in compassionate use, but the indications aren't known
bosutinib	CML	it has Hungarian registration, it hasn't marketed yet in reimbursed framework
enzalutamide	prostate	reimbursed submission was submitted, decision hasn't been yet
lenilidomide	MDS	its usage was allowed several times by NIP*, it has turnover in compassionate use
panitumumab	CRC	reimbursed under itemized accounting in first, second and third line treatment of unresectable metastatic colorectal carcinoma in KRAS wild type (its official registered indication have already included the RAS wilde type not only the KRAS)
pertuzumab	breast	its usage was allowed once by NIP*
pomalidomide	MM	it isn't available in Hungary, it hasn't got Hungarian registration
panatinib	CML	its usage was allowed two times by NIP* in other indication, it hasn't got Hungarian registration
regorafenib	GIST	its usage was allowed once by NIP*, it has Hungarian registration
trastuzumab	breast	reimbursed under itemized accounting in IHC HER2+++ or FISH positive breast carcinoma
vismodegib	BCC	reimbursed submission was submitted, decision hasn't been yet

CRC=colorectal carcinoma, CML=chronic myelogenous leukemia, MDS= myelodysplastic syndrome, MM= multiple myeloma, GIST=gastrointestinal stromal tumour, BCC=basal cell carcinoma

*Source: Public list of off-label indication applications of National Institute of Pharmacy ([link](#))