

News, current issues

- **Legislations** come into force between 01/03/2017 and 01/04/2017: Act LXXXIII of 1997 (01.04.2017); NM Decree No.9/1993. (01.04.2017); Gov.Decree No.43/1999. (01.04.2017); Gov.Decree No.235/2009. (01.04.2017); Gov.Decree No.313/2011. (01.04.2017); EüM Decree No.4/2000. (01.04.2017); EüM Decree No.43/2005. (01.04.2017); EüM Decree No.52/2005. (01.04.2017); EüM Decree No.13/2009. (01.04.2017); EMMI Decree No.15/2012. (01.04.2017)
- **NEWS[HUN]:** "Hungarian national oncogenomics program" [link](#)
- **NEWS[HUN]:** "Big producer invests more in Hungary" [link](#)
- **NEWS[HUN]:** "Less EU assistance for healthcare" [link](#)
- **NEWS[EN]:** "FDA hits the ground running with 12 first-quarter 2017 drug-approvals" [link](#)
- **NEWS[EN]:** "Brexit: EU drug agency prepares to leave London" [link](#)
- **NEWS[HUN]:** "Number of diabetes patients doubled in 12 years" [link](#)
- **NEWS[HUN]:** "Hungarian authorisation process is slow" [link](#)

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Health Security Fund	2016. I-XII.	2017 appropriation (1 Jan)	2017		
			I-II. months	% of appropriation	% of last year
Total of Budgetary Expenditures	2 133,1	2 139,5	345,3	96,8%	109,1%
Curative preventive provisions	1 089,9	1 121,4	173,7	92,9%	113,0%
Contracted specialty care	683,3	801,3	115,3	86,3%	115,2%
Medicine subsidies (pharmacy)	327,9	313,0	55,6	106,6%	104,8%
Total of Budgetary Revenues	2 043,9	2 059,1	357,0	104,0%	103,5%
Social Security Contributions	1 479,5	1 532,4	264,6	103,6%	106,1%
Contribution of Pharmaceutical Manufacturers and Wholesalers	71,6	66,0	11,0	100,4%	115,5%
Balance			11,7		41,1%

Billion HUF

In expenditures and revenues of 2017 budget, there is 4.86% increase compared to appropriation of 2016 but only 0.3% increase compared to fulfilment, despite that the appropriation of expenditures were raised with 80 billion HUF. Revenues of Social security contributions are 52.9 billion HUF (3.6%) higher, while Contribution of manufacturers and wholesalers are 26 billion HUF (6.2%) lower in the appropriation of 1st of January, than in the last year's fulfilment. The pharmaceutical budget was planned to be 23.6 billion HUF (8.2%) higher than the last year appropriation (without the special budget drugs), and 9.2 billion HUF (2.9%) lower than the last year fulfilment.

In the first two months of 2017, we can see 3.28% surplus in Health Security Fund, compared to the prorated appropriation of expenditures. Fulfilment of medicine subsidies is 6% higher than periodic appropriation as a result of the medicines' higher turnover particularly that reimbursement based on special permission.

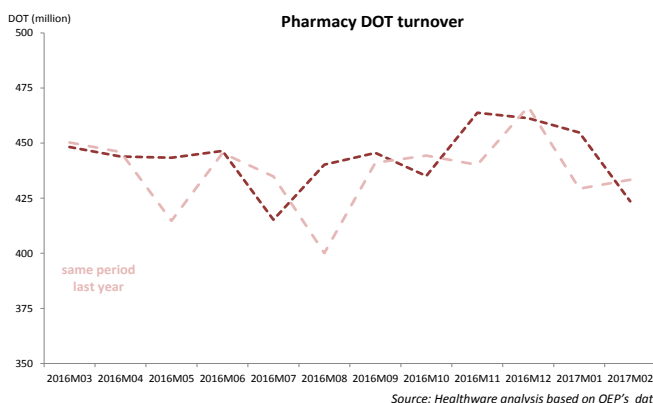
Changes to subsidised medicinal product categories

Changes in the public drug list	2016 Nov.	2016 Dec.	2017 Jan.	2017 Feb.	2017 Mar.	2017 Apr.	2017
Number of new products	32	12	25	13	12	22	72
Number of new AI	15	0	6	1	2	1	10
Number of delisted products	28	33	21	228	10	26	285
Prices							
Decrease	11	5	11	4	4	85	104
Increase	1	0	3	3	0	0	6

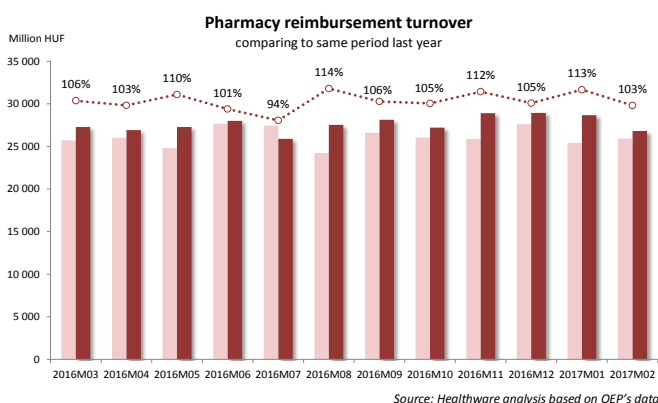
Changes in the public drug list	2016 Nov.	2016 Dec.	2017 Jan.	2017 Feb.	2017 Mar.	2017 Apr.	2017
Reimbursement							
Decrease	5	4	27	2	4	314	347
Increase	5	0	6	3	0	57	66
Co-payment							
Decrease	19	5	20	8	5	154	187
Increase	1	0	17	3	0	258	278

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

Prescription drugs' DOT turnover in 2016 was 1.18% higher than in 2015, so the trend of drug consumption is still increasing, but in slower rate than in 2014 (2.74%) or 2013 (2.23%). Meanwhile, the reimbursement turnover was higher with 5.56%, because of the additional 14.2 billion HUF fulfilment of special permission appropriation, the 6% growth of reimbursement turnover of out-of-fix group products, and stagnation of fixed market. The average reimbursement per DOT was higher with 4.33% than the 2015's average. New ATCs that got authorized in 2014-2016 generated 7.6% of annual reimbursement turnover, while only 1.1% of annual DOT turnover.

Drug sales in the first two months of 2017 was 1,82% higher than the same period last year, while the average reimbursement per DOT increased with 6.11%. The reimbursement turnover was higher with 8,05% 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



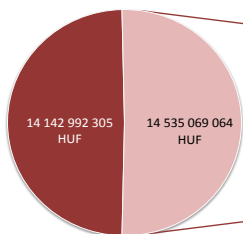
Market data

Marketing authorisation information

2016	EMA	OGYI	2016 - Q4	EMA	OGYI	February 2017	EMA	OGYI
New brands	77	173	New brands	15	45	New brands	4	14
New SKUs	697	1 765	New SKUs	183	472	New SKUs	34	107

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

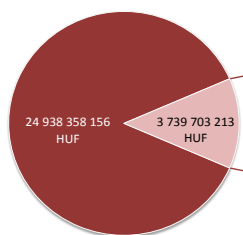
TOP10 DISTRIBUTOR by all reimbursement paid in February 2017



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 833 263 476 HUF
SANOFI-AVENTIS Zrt.	1 915 018 940 HUF
EGIS Gyógyszergyár Zrt.	1 430 909 114 HUF
TEVA Gyógyszergyár Zrt.	1 421 777 612 HUF
Pfizer Kft.	1 414 767 958 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 372 499 332 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató Kft.	1 300 118 665 HUF
Novo Nordisk Hungária Kft.	1 056 132 457 HUF
Sandoz Hungária Kereskedelmi Kft.	991 406 471 HUF
Boehringer Ingelheim Pharma Gesellschaft m. b. H. Magyarország	799 175 038 HUF

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

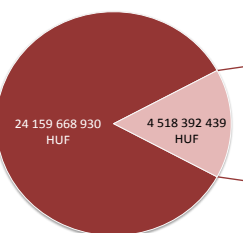
TOP10 BRAND by all reimbursement paid in February 2017



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	662 464 613 HUF
GLIVEC	Novartis Hungária Kft.	513 452 922 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	481 009 095 HUF
TECFIDERA	Biogen Hungary Korlátolt Felelősségű Társaság	314 541 986 HUF
XARELTO	Bayer Hungária Kereskedelmi és Szolgáltató Kft.	305 216 298 HUF
TASIGNA	Novartis Hungária Kft.	303 733 894 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m. b. H. Magyarország	298 734 806 HUF
IMBRUVICA	Janssen-Cilag Gyógyszerkereskedelmi Market	297 398 927 HUF
SUTENT	Pfizer Kft.	286 620 116 HUF
HUMULIN	Lilly Hungaria Kft.	276 530 556 HUF

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

TOP10 ATC by all reimbursement paid in February 2017



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	662 464 613 HUF
N05AX13	paliperidon	621 611 270 HUF
V06D	egyéb tápszerek	587 977 123 HUF
L01XE01	imatinib	517 678 361 HUF
C10AA07	rosuvastatin	435 387 953 HUF
A10AE04	insulin glargine	425 788 673 HUF
A10AB01	insulin (human)	330 186 068 HUF
C09BA04	perindopril és vizelethajtók	317 540 094 HUF
N07XX09	dimetil-fumarát	314 541 986 HUF
B01AX06	rivaroxaban	305 216 298 HUF

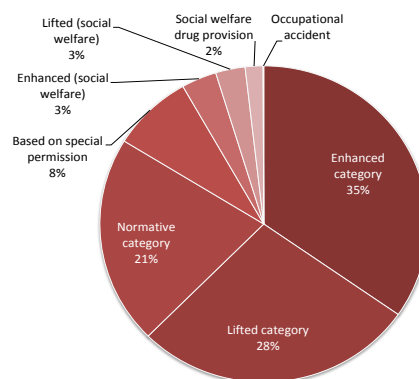
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Average number of medical sales reps; 02/2017

Medicinal products	1 495	Medical aids + nutritions	2
Medicinal products + aids	264	Nutritions	121
Medicinal products + nutritions	12	All	1 937
Medical aids	264		

Source: Healthware analysis based on OGYI's

Drug reimbursement by legal title; 02/2017



Source: Healthware analysis based on the sales

TOP10 ATC by number of patients in February 2017

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetilszalicilsav	351 509
C09BA04	perindopril and diuretics	298 320
C07AB12	nebulolol	256 661
C08CA01	amlodipin	254 852
A02BC02	pantoprazol	237 718
J01CR02	amoxicillin - laktamázgátló kombinációk	236 803
C10AA07	rosuvastatin	225 004
A11CC05	kolekalciferol	224 263
M04AA01	allopurinol	214 466
C10AA05	atorvastatin	212 821

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

The Technical Guideline on the Methodology of Health-Economic Analyses and Conducting Cost-Effectiveness Analyses by the Ministry of Human Resources

The updated guideline on cost-effectiveness analysis¹ announced on the 20th February 2017 considering latest international guidelines and finalized in collaboration with local experts. The updated version provides more detailed description and in certain cases contains clarified recommendations. The strengths of the recommendations express by different terminology which are the following in increasing order of strength: must, necessary, expected, recommended/suggested, practical. Obvious judgement of these recommendations will reach by everyday practice.

The following is a summary of the most important changes and recommendations.

Choice of comparator

- Several recommendations of the guideline is about the choice of comparator. Normally, the comparator(s) should be the current reimbursed standard therapy or therapies indicated in the relevant disease. Beyond that, comparisons based on directly comparing clinical trials are preferred, even though the comparison not based on the current standard therapy. On this basis, 2 strategies are available for the choice of comparator: either on the basis of available evidences (therefore, based on the available, if possible, head-to-head clinical trials, systematic reviews etc.), or on the basis of replacing factors (therefore, the product should be compared with the cheapest therapy or with the therapy with the highest turnover). Irrespectively of the used strategy, explanation and substantiation are extremely important.
- The guideline specifies the preferred order of evidences in accordance with the choice of comparison, which applies to the estimation of number of patients (1. turnover data, 2. market research, 3. specialist consultation, 4. registries, 5. updated local clinical protocols, 6. internet searching).
- If there is no single well-defined comparator, the analysis should use several comparators collectively for the comparison.

Health services – therapeutic need

- The guideline expects broader outlook and introduction in regard to the medical background of the analyses. Presentation of all clinical trials of the relevant treatment is necessary, which promotes the decision maker to get acquainted with the profile and the therapeutic potential of the treatment.

- Effectiveness data - meaning real data - is preferred over efficacy data. If local effectiveness data not available, it is recommended to use international long-term data. In case of the absence of these data, clinical trial data should be used.

Health economic analysis

- An important change, that analytical techniques used hitherto expanded with cost-consequences analysis. Compared with methods used hitherto (cost-effectiveness, cost-utility and cost-minimization analysis), the use of cost-consequences analysis allows the measure of connections between costs in case of the absence of non-inferiority test. QALY-based cost-utility analysis has remained the first-choice method.
- The cost of health technologies must be whole prices, which means gross consumer price in case of medicines with pharmaceutical turnover and gross wholesale price in case of hospital medicines and itemized accounting (thus, in any event VAT should be taken in account).
- Another important change, that background calculation tables are parts of the analysis, so delivery of those for the Department of Health Technology Assessment is necessary, since just health economic analyses submitted on the correct form based on substantive and formal requirements are appraisable.
- Instead of the interval threshold used hitherto, concrete threshold has defined. On this basis, technologies with ICER more than three times the value of the Hungarian GDP per capita can not be considered as cost-effective.
- The guideline emphasises the specification of methods and sources of estimating the number of patients in order to estimation of uncertainties be as small as possible and in order to estimation be as reliable as possible.

Let us thank the employees of the Division of Health Technology Assessment for their assistance in interpretations of the updated guideline.

For further information, please contact our consultants!

¹The Technical Guideline on the Methodology of Health-Economic Analyses and Conducting Cost-Effectiveness Analyses by the Ministry of Human Resources. In force from 20th February 2017. Published in Egészségügyi Közlemények 2017/3.