No.11, Issue IV. November 2016
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Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE

News, current issues

- **Legislations** come into force between 01/01/2016 and 01/02/2016**:** NM Decree No.9/1993. (01.11.2016); EüM Decree No.31/2010. (01.11.2016); NEFMI Decree No.12/2011. (04.10.2016)
- **STUDY[EN]:** *"Health at a Glance: Europe 2016"* link
- **NEWS[HU]:** *"OEP: Tax payment obligation due to expenditure surplus in the first 9 months in 2016"* link
- **NEWS[HU]:** *"Drug expenses in the mirror of reality"* link
- **NEWS[HU]:** *"Too bad for chancellery system"* link
- **NEWS[HU]:** *"Ónodi-Szűcs: Sixty billion to the hospitals"* link
- **NEWS[HU]:** *"Lack of one-day care due to parasolvency"* link
- **NEWS[EN]:** *"Richter's generic osteoporosis drug gets EU recommendation"* link

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund

Billion HUF

Health Security Fund	2015. I-XII.	2016 original appropriation	2016		
			I-IX. months	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 955,3**	**1 963,7**	**1 502,9**	**102,0%**	**104,0%**
Curative preventive provisions	960,6	982,4	734,1	99,6%	103,8%
Medicine subsidies	326,2	305,1	252,3	110,3%	105,1%
Medicine subsidies (pharmacy)	310,6	231,4	241,8	139,3%	104,6%
Total of Budgetary Revenues	**1 925,4**	**1 963,7**	**1 514,9**	**102,9%**	**105,0%**
Social Security Contributions	1 223,4	1 417,0	1 093,7	102,9%	120,1%
Contribution of Pharmaceutical Manufacturers and Wholesalers	65,3	58,0	54,6	125,5%	110,4%
Balance	**-29,9**	**0,0**	**12,0**		**-491,7%**

In expenditures and revenues of 2016 budget, there is 2,77% increase compared to appropriation of 2015 and 0,43% increase compared to fulfilment of 2015. The central budget contribution is planned to be less with 26,5% than last year fulfilment, and this gap is filled with the 18,2% higher social security contribution (218 billion HUFs). The medicine subsidies plan is lower with 21,2 billion HUFs than last year expenses, but higher with 7 billion HUFs than the last year's original appropriation.
In the first nine months of 2016 the Health Security Fund produced a 0,82% surplus due to the higher social security contributions (+30,9 billion HUFs; +2,9%) and the lower expenditures of curative preventive provisons (-17 billion HUFs; -2,3%). Medicine subsidies shows 10,3% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission (+9,5 billion HUFs; +157%), and reimbursement of medicines without reference price group.

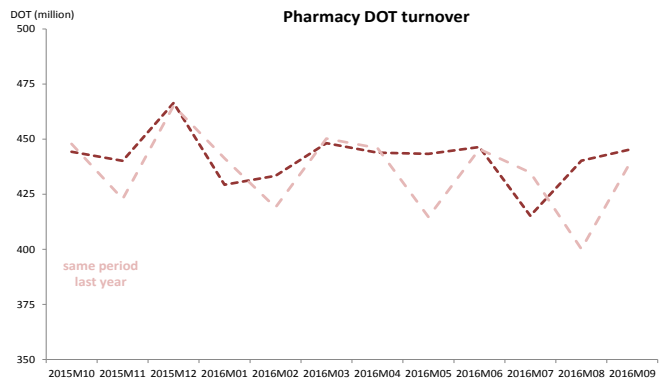
Changes to subsidised medicinal product categories

Changes in the public drug list	2016 June	2016 July	2016 Aug.	2016 Sep.	2016 Oct.	2016 Nov.	2016
Number of new products	17	9	15	47	31	32	194
Number of new AI	0	2	0	0	3	15	11
Number of delisted products	1	11	31	6	10	28	168
Prices							
Decrease	0	43	2	3	98	11	245
Increase	0	5	0	0	1	1	9

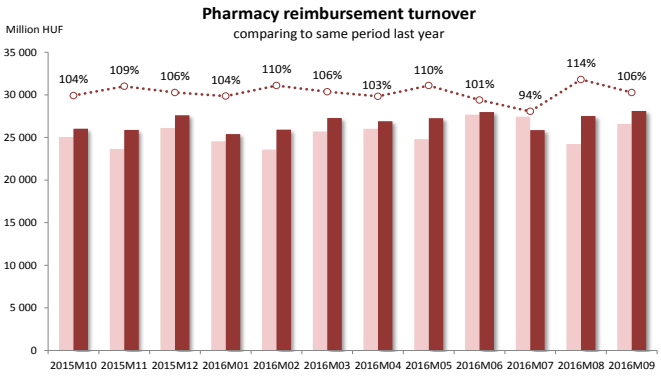
Changes in the public drug list	2016 June	2016 July	2016 Aug.	2016 Sep.	2016 Oct.	2016 Nov.	2016
Reimbursement							
Decrease	0	53	0	5	237	5	498
Increase	0	6	36	0	28	5	234
Co-payment							
Decrease	0	52	2	7	150	19	490
Increase	0	23	36	1	152	1	352

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 2015 was 1,04% higher than in 2014, so the trend of drug consumption is still increasing, but in slower rate than in 2014 (2,74%) or 2013 (2,23%); while the reimbursement turnover was higher with 7,44%. The average reimbursement per DOT was higher with 6,34% than the 2014's average. New innovative reimbursement decisions were made in 2014 and 2015 generated 3,1% and 0,65% of annual reimbursement turnover, while only 0,4% of annual DOT turnover.
Drug sales in the first nine months of 2016 was 1,35% higher than the same period last year, while the average reimbursement per DOT increased with 3,69%. The reimbursement turnover was higher with 5,09% for this period compared to last year.

Indicator system development

Quality indicators are needed for evaluate a therapy at macro level. The individual micro-level knowledge enables to seek/ elaborate parameters which allow to build up an indicator system. With the comprehensive knowledge acquired along our micro-level analysis products we can ensure elaboration of systems, which show the success of certain medical technologies in transparent way, with objective parameters.

Downloadable document: The domestic experiences of the „Changing Diabetes Baromèter" program IME, 2011

More about the service: link

Product offering

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Market data

Marketing authorisation information

2015	EMA	OGYI
New brands	91	190
New SKUs	1 081	2 233

2016 - Q3	EMA	OGYI
New brands	15	30
New SKUs	79	267

September 2016	EMA	OGYI
New brands	2	4
New SKUs	9	12

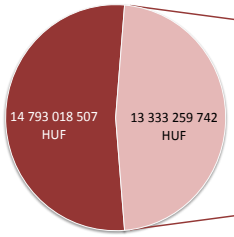
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 09/2016

All	1 784
Medicinal products	1 508
Medical aids	245
Both	31

Source: Healthware analysis based on OGYI's

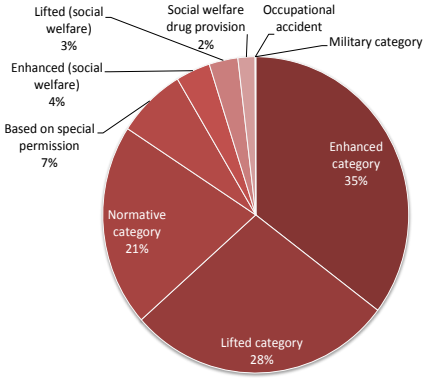
TOP10 DISTRIBUTOR by all reimbursement paid in September 2016



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 676 500 974 HUF
SANOFI-AVENTIS Zrt.	1 888 142 266 HUF
EGIS Gyógyszergyár Zrt.	1 425 615 366 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 316 824 947 HUF
Pfizer Kft.	1 175 830 512 HUF
TEVA Gyógyszergyár Zrt.	1 104 015 650 HUF
Novo Nordisk Hungária Kft.	1 058 175 424 HUF
Sandoz Hungária Kereskedelmi Kft.	974 883 678 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató K!	868 866 484 HUF
Lilly Hungaria Kft.	844 404 440 HUF

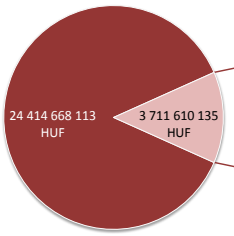
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 09/2016



Source: Healthware analysis based on the sales

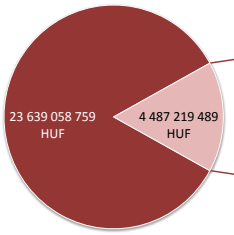
TOP10 BRAND by all reimbursement paid in September 2016



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	637 367 297 HUF
GLIVEC	Novartis Hungária Kft.	543 945 596 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	476 521 751 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m.	313 498 432 HUF
TASIGNA	Novartis Hungária Kft.	304 468 752 HUF
TECFIDERA	Biogen Hungary Korlátolt Felelősségu Társaság	301 888 923 HUF
LANTUS	SANOFI-AVENTIS Zrt.	291 973 733 HUF
SUTENT	Pfizer Kft.	290 595 273 HUF
HUMULIN	Lilly Hungaria Kft.	286 595 921 HUF
XARELTO	Bayer Hungária Kereskedelmi és Szolgáltató K!	264 754 458 HUF

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

TOP10 ATC by all reimbursement paid in September 2016



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	637 367 297 HUF
V06D	other nutrients	610 404 936 HUF
N05AX13	paliperidone	544 581 509 HUF
L01XE01	imatinib	543 945 596 HUF
C10AA07	rosuvastatin	434 005 388 HUF
A10AE04	insulin glargine	426 208 079 HUF
A10AB01	insulin (human)	343 481 808 HUF
C09BA04	perindopril and diuretics	323 936 124 HUF
R03BB04	tiotropium bromide	313 498 432 HUF
L02AE02	leuprorelin	309 790 320 HUF

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

TOP10 ATC by number of patients in September 2016

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	353 137
C09BA04	perindopril and diuretics	295 836
C08CA01	amlodipine	253 396
C07AB12	nebivolol	251 123
A02BC02	pantoprazole	229 248
C10AA07	rosuvastatin	224 139
C10AA05	atorvastatin	217 366
M04AA01	allopurinol	215 309
A11CC05	colecalciferol	183 689
C09AA04	perindopril	179 519

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

Availability of biosimilars in Europe and Hungary — Case study

In our November case study we comprehensively reviewed the European market of biosimilars. In our analysis we compared the available biosimilars in Europe and in Hungary, also highlighting more aspects, just like the type of producers, the therapy areas, and the involved regions. Biosimilars importance regarding the finance systems is - as well as in case of regular medications - that they can be produced more cost-effectively than the original product, which is significant due to the high prices of biotechnological products[1]. Since their production is time-consuming and expensive, differently from the prices of generic products, their prices are high as well.

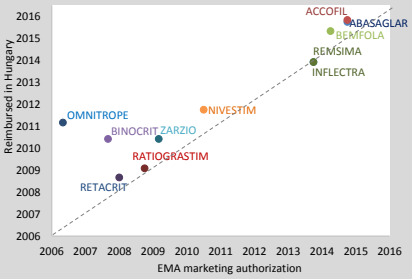
> In case of application of biosimilars it is very important to note that they cannot automatically replace the original product, since they are not equivalent. In Europe the accepted method is that only doctors can decide that the switch can happen, and they observation is needed. Therefore the authorization of a biosimilar does not mean that patients switch-off to the cheaper version only in order to cost-effectiveness, except for the case of those patients who are resistant to the original substance[2] [3].

Currently in Europe twenty three biosimilars are authorized by the European Medicines Agency (EMA), which are following therapies of nine substances in sum, and mainly used in treating autoimmune or chronic diseases, or in case of cancer[4]. Comprehensive directives of EMA were emitted after 2014, although product-specific directives were emitted in 2006 already. In that year were authorized the production of the first biosimilar in Europe, which was *somatropine*[5]. In Hungary, eleven out of the twenty three biosimilars are authorized, so almost the half of the available products[6].

INN	Therapy area	Biosimilars authorized in Europe	Biosimilars applied in Hungary
enoxaparin sodium	Venous Thromboembolism	Inhixa, Thorinane	
epoetin alfa	Anemia, Cancer, Chronic Kidney Failure	Abseamed, Binocrit, Epoetin Alfa Hexal	Binocrit
epoetin zeta	Anemia, Autologous Blood Transfusion, Cancer, Chronic Kidney Failure	Retacrit, Silapo	Retacrit
etanercept	Arthritis, Psoriatic Arthritis, Rheumatoid Psoriasis	Benepali	
filgrastim	Cancer, Hematopoietic Stem Cell Transplantation, Neutropenia	Accofil, Biograstim, Filgrastim Hexal, Grastofil, Nivestim, Ratiograstim, Tevagrastim, Zarzio	Accofil, Nivestim, Ratiograstim, Zarzio
follitropin alfa	Anovulation	Bemfola, Ovaleap	Bemfola
infliximab	Arthritis, Psoriatic Arthritis, Rheumatoid Colitis, Ulcerative Crohn Disease, Psoriasis, Ankylosing Spondylitis	Flixabi, Inflectra, Remsima	Inflectra, Remsima
insulin glargine	Diabetes Mellitus	Abasaglar	Abasaglar
somatropin	Pituitary Dwarfism, Prader-Willi Syndrome, Turner Syndrome	Omnitrope	Omnitrope

After examining the producers of biosimilars used in Europe and Hungary, we came to the conclusion that generic firms with original parent company take the majority of them. Such firms also producing for the Hungarian market are Hospira and Sandoz, producers of biosimilars of *epoetin zeta* and *infliximab* besides *filgrastim*.

Generic producers who have turnover in Hungary with the biosimilars of *infliximab* are Accord and Ratiopharm. Finox and Celltrion, producers of biosimilars of *follitropin alfa* and *infliximab* are specialized on producement of biosimilars which are also used in Hungary. Among producers of authorized products in Europe we can find an actor from another industry, Samsung Bioepis, which is a subsidiary of Samsung specialized on producing biosimilars, producing the biosimilar of the substance *etanercept*, which is not authorized in Hungary. The figure on the right represents the data of products getting reimbursed in Hungary in comparison with the data of EMA authorization, so it is significant, that the difference in most of the cases is relatively small. Therefore we can come to the conclusion that in Hungary reimbursed biosimilars get financed quite soon, although there are several INNs that have biosimilars not yet available here.



Region (Number of brands (Number of active agents))	Type of producer: Innovative	Generic, innovative parent undertaking	Generic	Other
Europe		8 (5)	7 (5)	
North-America	1 (1)		1 (1)	
Middle-East			2 (2)	
Asia				4 (3)

Among the producers of biosimilars authorized in Europe we can find mostly European firms besides Chinese, Souhtern Korean, Canadian, Israeli, United States and Indian producers. In the USA the directives of Obamacare ensure optimalized conditions for authorization of biosimilars[7]. Biosimilar got authorized in 2015 for the first time in USA, and in 2016 three further products were authorized[8] [9] [10]. The last one was the biosimilar of *adalimumab*, which is the only one authorized in the United States but not in Europe[11].

Further possible research object might be the total number of biological therapies registered in Europe, the time between the end of the absolute monopoly and the first biosimilar of the given product getting registered, coverage and delays of reimbursement Europe-wide, and mapping of special financing technologies.

[3] Dr. Kerpel-Fronius Sándor: Biológiai gyógyszerek ártámogatása klinikai farmakológiai nézőpontból. IME IX. évfolyam 8. szám 2010. október

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