No.7, Issue IV. July 2016
Published: 19 July 2016

Actualities of Hungarian pharmaceutical financing market

Newsletter

HEALTHWARE CONSULTING LTD.

News, current issues

- **Legislations** come into force between 01/06/2016 and 01/07/2016: Gov.Decree No.235/2009. (01.07.2016); Gov.Decree No.323/2010. (01.07.2016); NEFMI Decree No.11/2011. (11.07.2016); Act XI of 1991 (01.07.2016); Act CLIV of 1997 (01.07.2016); Act XXV of 1998 (01.07.2016); Act XCV of 2005 (01.07.2016); Act XCVII of 2006 (01.07.2016); Act XCVIII of 2006 (01.07.2016)

- **NEWS:** *"Proposed ammendments of NM Decree No.9/1993. were published"* link
- **NEWS:** *"Super hospitals and fifty billion for healthcare"* link
- **NEWS:** *"Modifications in indication points of ESzCsM Decree No.32/2004. were announced"* link
- **NEWS:** *"Depression decreases adherence of COPD patients"* link
- **NEWS:** *"Brexit spells upheaval for EU and UK drug regulation"* 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-V. months	% of appropriation	% of last year
Total of Budgetary Expenditures	**1 955,3**	**1 963,7**	**817,0**	**99,9%**	**106,1%**
Curative preventive provisions	960,6	982,4	395,2	96,5%	101,5%
Medicine subsidies	326,2	305,1	137,2	107,9%	104,4%
Medicine subsidies (pharmacy)	310,6	231,4	131,8	136,7%	103,9%
Total of Budgetary Revenues	**1 925,4**	**1 963,7**	**848,7**	**103,7%**	**105,1%**
Social Security Contributions	1 223,4	1 417,0	611,6	103,6%	120,1%
Contribution of Pharmaceutical Manufacturers and Wholesalers	65,3	58,0	32,2	133,3%	113,8%
Balance	**-29,9**	**0,0**	**31,7**		**83,6%**

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 five months of 2016 the Health Security Fund produced a 3,87% surplus due to the higher social security contributions (+21,17 billion HUFs; +3,7%) and the lower expenditures of curative preventive provisons (-14,12 billion HUFs; -3,5%). Medicine subsidies shows 7,9% surplus as a result of the medicines' higher turnover particularly that reimbursement based on special permission, and reimbursement of medicines without reference price group.

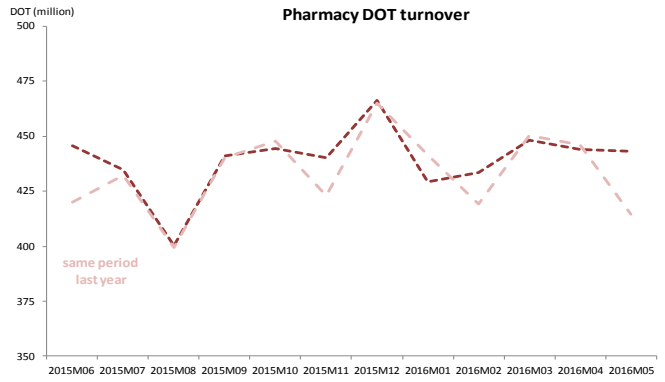
Changes to subsidised medicinal product categories

Changes in the public drug list	2016 Feb.	2016 Mar.	2016 Apr.	2016 May	2016 June	2016 July	2016
Number of new products	9	19	12	7	17	9	101
Number of new AI	0	1	0	0	0	2	8
Number of delisted products	18	9	36	19	1	11	121
Prices							
Decrease	3	5	59	1	0	43	142
Increase	0	0	3	0	0	5	8

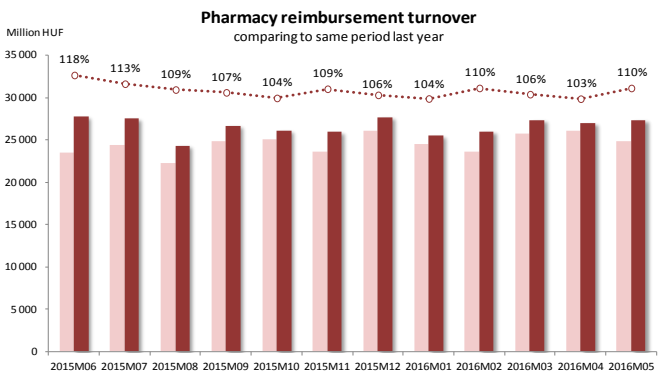
Changes in the public drug list	2016 Feb.	2016 Mar.	2016 Apr.	2016 May	2016 June	2016 July	2016
Reimbursement							
Decrease	1	6	155	1	0	53	256
Increase	2	0	138	0	0	6	170
Co-payment							
Decrease	4	6	200	2	0	52	331
Increase	0	1	123	0	0	23	163

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 five months of 2016 was 0,2% lower than the same period last year, while the average reimbursement per DOT increased with 6,75%. The reimbursement turnover was higher with 6,54% for this period compared to last year.

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Market data

Marketing authorisation information

2015	EMA	OGYI
New brands	91	190
New SKUs	1 081	2 226

2016 - Q1	EMA	OGYI
New brands	22	32
New SKUs	257	411

May 2016	EMA	OGYI
New brands	11	19
New SKUs	41	195

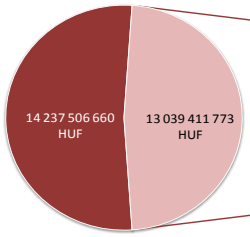
Source: Healthware analysis based on OGYI's and EMA's data

Average number of medical sales reps; 05/2016

All	1 784
Medicinal products	1 525
Medical aids	242
Both	17

Source: Healthware analysis based on OGYI's

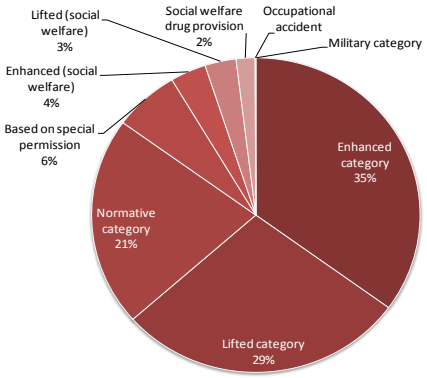
TOP10 DISTRIBUTOR by all reimbursement paid in May 2016



TOP 10 - DISTRIBUTOR	Reimbursement
Novartis Hungária Kft.	2 555 991 343 HUF
SANOFI-AVENTIS Zrt.	1 783 799 917 HUF
EGIS Gyógyszergyár Zrt.	1 400 927 891 HUF
Richter Gedeon Vegyészeti Gyár NyRt.	1 301 266 100 HUF
TEVA Gyógyszergyár Zrt.	1 175 303 655 HUF
Pfizer Kft.	1 165 980 256 HUF
Novo Nordisk Hungária Kft.	1 027 914 833 HUF
Sandoz Hungária Kereskedelmi Kft.	914 259 088 HUF
Janssen-Cilag Gyógyszerkereskedelmi Marketing Szolgáltató K	860 951 506 HUF
Lilly Hungaria Kft.	853 017 184 HUF

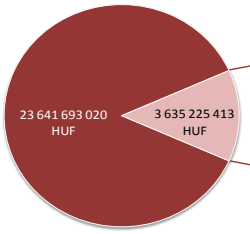
Source: Healthware analysis based on the sales turnover that pharmacies produced from POM

Drug reimbursement by legal title; 05/2016



Source: Healthware analysis based on the sales

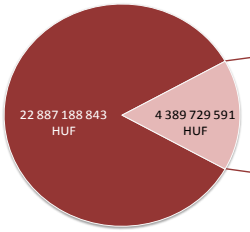
TOP10 BRAND by all reimbursement paid in May 2016



TOP 10 - BRAND	Distributor	Reimbursement
CLEXANE	SANOFI-AVENTIS Zrt.	607 740 459 HUF
GLIVEC	Novartis Hungária Kft.	518 632 758 HUF
XEPLION	Janssen-Cilag Gyógyszerkereskedelmi Market	457 011 754 HUF
SPIRIVA	Boehringer Ingelheim Pharma Gesellschaft m.	331 751 549 HUF
LANTUS	SANOFI-AVENTIS Zrt.	310 689 150 HUF
TASIGNA	Novartis Hungária Kft.	296 592 120 HUF
HUMULIN	Lilly Hungaria Kft.	289 558 795 HUF
SUTENT	Pfizer Kft.	287 312 380 HUF
TECFIDERA	Biogen Idec Hungary Kft.	286 607 606 HUF
FOSTER	Chiesi Hungary Kft.	249 328 843 HUF

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

TOP10 ATC by all reimbursement paid in May 2016



TOP 10 - ATC	International non-proprietary name (INN)	Reimbursement
B01AB05	enoxaparin	607 740 459 HUF
V06D	other nutrients	597 009 237 HUF
N05AX13	paliperidone	527 348 872 HUF
L01XE01	imatinib	518 632 758 HUF
C10AA07	rosuvastatin	439 173 239 HUF
A10AE04	insulin glargine	400 616 567 HUF
A10AB01	insulin (human)	344 842 586 HUF
R03BB04	tiotropium bromide	331 751 549 HUF
C09BA04	perindopril and diuretics	326 022 205 HUF
L01XE08	nilotinib	296 592 120 HUF

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

TOP10 ATC by number of patients in May 2016

TOP 10 - ATC	International non-proprietary name (INN)	Patients
B01AC06	acetylsalicylic acid	354 975
C09BA04	perindopril and diuretics	300 564
C08CA01	amlodipine	265 127
C07AB12	nebivolol	255 023
C10AA07	rosuvastatin	229 104
C10AA05	atorvastatin	224 887
A02BC02	pantoprazole	213 727
M04AA01	allopurinol	210 763
C09AA04	perindopril	184 177
C07AB07	bisoprolol	173 359

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

PRIME – PRIority MEdicines— Case study

Introduction

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. Many patients with serious diseases have no or only unsatisfactory therapeutic options and should be able to benefit from scientific advancement and cutting edge medicines as early as possible. PRIME scheme – established in March 2016 – builds on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment.

Accelerated assessment

The accelerated assessment process is intended to reduce the timeframe for the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) to review a marketing-authorisation application. It is beneficial for the manufacturers as their product can be marketed earlier. Eligibility criteria – just as in the PRIME scheme – is that the product should have a major public health interest and should offer a therapeutic innovation (CHMP decides whether the product fulfils these criteria). Evaluating a marketing-authorisation application under the centralized procedure can take up to 210 days, not counting clock stops when applicants have to provide additional information. On request, the CHMP can reduce the timeframe to 150 days if the applicant provides sufficient justification for an accelerated assessment. Compared to the standard accelerated assessment process, it is now possible through the PRIME scheme that applicants receive confirmation during the clinical development phase that their medicine might potentially be eligible for accelerated assessment. By engaging with medicine developers early on, PRIME is aimed at improving clinical trial designs so that the data generated is suitable for evaluating a marketing-authorisation application. Furthermore, early dialogue and scientific advice also ensure that patients only participate in trials designed to provide the data necessary for an application, making the best use of limited resources.

Key benefits for patients

PRIME is driven by patients' needs. It focuses on medicines that offer a major therapeutic advantage over existing treatments, or benefit patients with no current treatment options for their disease. It helps to translate research into the development of medicines while meeting regulatory requirements. The main goal of PRIME is to bring promising treatments to patients earlier, without compromising high evaluation standards and patient safety.

Key benefits for medicine developers

PRIME helps developers of promising new medicines to optimize development plans, it speeds up the evaluation process, fosters early dialogue with EMA to facilitate robust data collection and high quality marketing authorization applications. In order to provide continuous support and help to build knowledge ahead of a marketing-authorisation application, a rapporteur is appointed from the CHMP or from the Committee on Advanced Therapies (CAT) for the applicants. Guidance on the overall development plan and regulatory strategy is provided as well, in the form of meetings with the rapporteur and a multidisciplinary group of experts. Another advantage is the presence of scientific advice at key development milestones, involving additional stakeholders such as health-technology-assessment bodies – which enhances faster access for patients.

Application procedure

Medicines eligible for PRIME must address an unmet medical need. Preliminary data must be available showing the potential to address this need and bring a major therapeutic advantage to patients. The applicant must complete an electronic form available on the PRIME website and the EMA will respond after 40 days.
As of May 2016 the EMA has received 27 PRIME applications. Most of the applications tend to focus on oncological (8 applications), infectious (4 applications), pulmonary and allergological (3 applications) diseases and the development of new vaccinations (3 applications). The following chart shows the six PRIME applications that has been accepted by the EMA:

Name	Therapeuthic indication	Type of applicant
CTL019	Treatment of paediatric patients with relapsed or refractory B cell acute lymphoblastic leukaemia	Other
Recombinant Vesicular Stomatitis Virus with Envelope Glycoprotein replaced by Zaire ebolavirus (Kikwit Strain) Glycoprotein	Vaccination against Ebola (Zaire strain)	Other
Aducanumab	Treatment of Alzheimer's disease	Other
CCX168	Treatment of patients with active ANCA-associated vasculitis (including granulomatosis with polyangiitis and microscopic polyangiitis)	SME
KTE-C19	Treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) who have not responded to their prior therapy, or have had disease progression after autologous stem cell transplant (ASCT)	SME
NI-0501	Treatment of primary haemophagocytic lymphohistiocytosis (HLH)	SME

*SME: Micro-, small- and medium-sized enterprises

In Hungary, non of these medicines are reimbursed, and no application for reimbursement has been made currently – most of these medicines are in the development phase.

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