News, current issues

News | In 4 years gratuity payments might disappear from the healthcare system »

News | There have been financial issues in the healthcare institutes »

News | Accrual based healthcare financing »

Decision-making index, June 2018

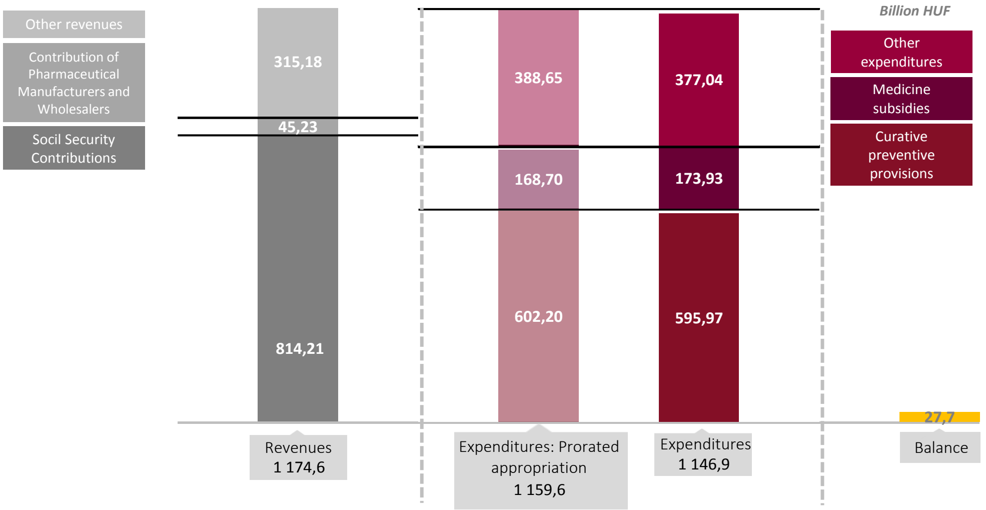
2,45

6/184		Legislation
112/184		Activity of Parliament
18/184		NIHIFM decisions

Methodology

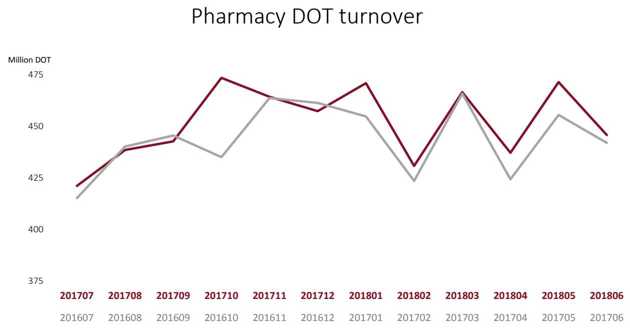
Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund, June 2018

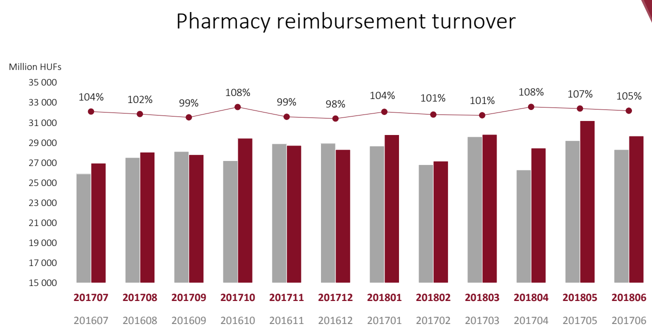


Source: Healthware analysis based on NHIFA data

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

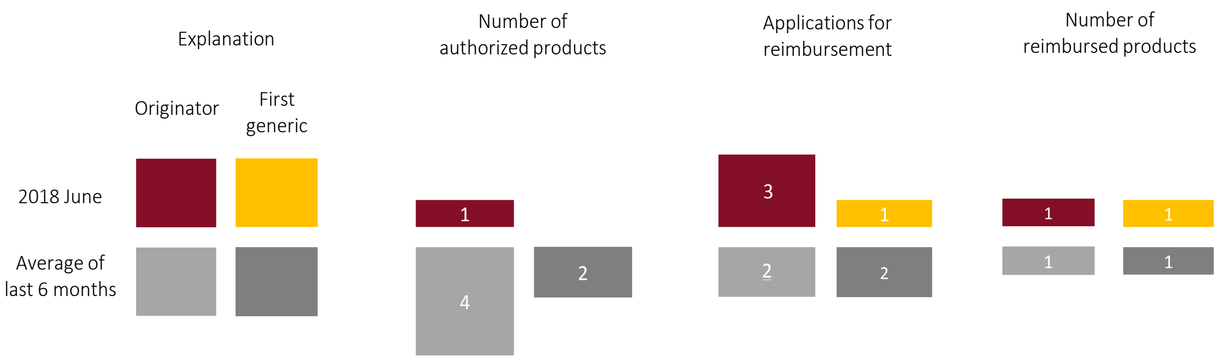


Source: Healthware analysis based on NHIFA data



Source: Healthware analysis based on NHIFA data

Changes to subsidized medicinal product categories, June 2018



Source: Healthware analysis based on NHIFA data

Product offering

Public turnover data in our Medalyse service

With our service Medalyse for our clients, public turnover data published by NHIFA is easily available and it is possible to follow them with time series analysis.

The turnover data is available on the following 16-18th day after the given month.

Healthware takes under to upload the data in the information system of Medalyse, if it is possible within 1 workday.

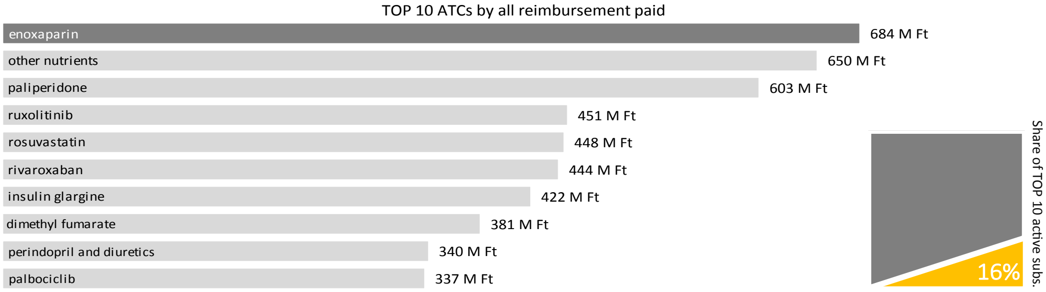
Therefore our clients are free to reach and analyze the turnover data of NHIF on the 20th day after the given month.

Detailed description about the data published by NHIFA: **link**

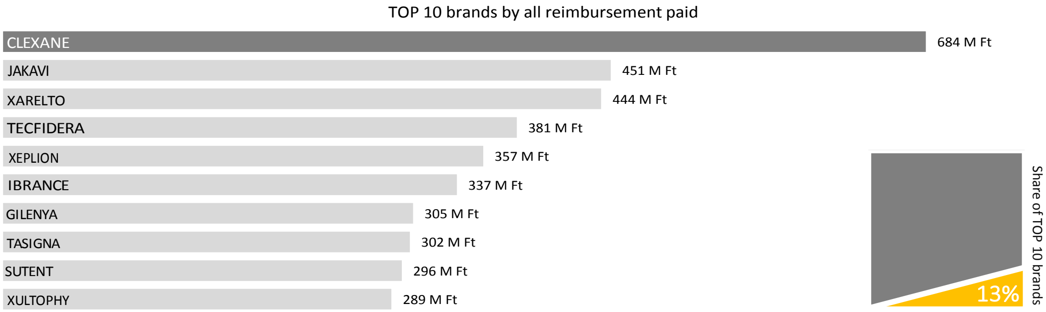
Details about Medalyse: **link**

Market data

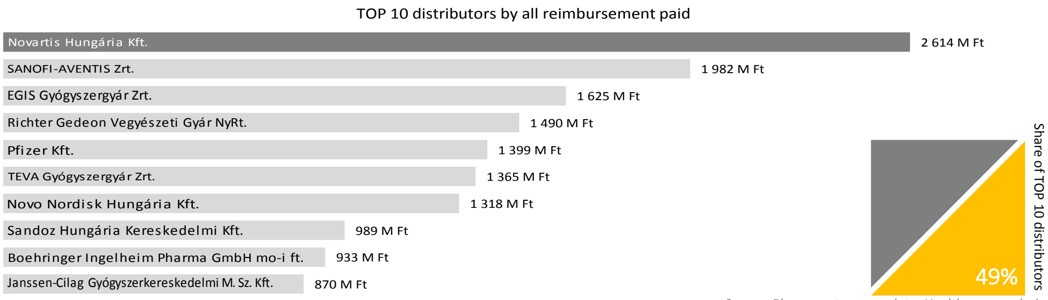
Toplists of reimbursement and number of patients, June 2018



Source: Pharmacy turnover data, Healthware analysis

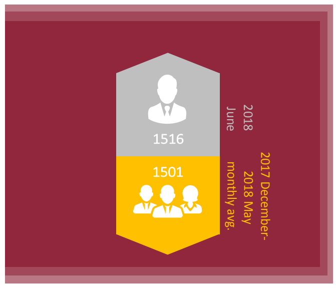


Source: Pharmacy turnover data, Healthware analysis

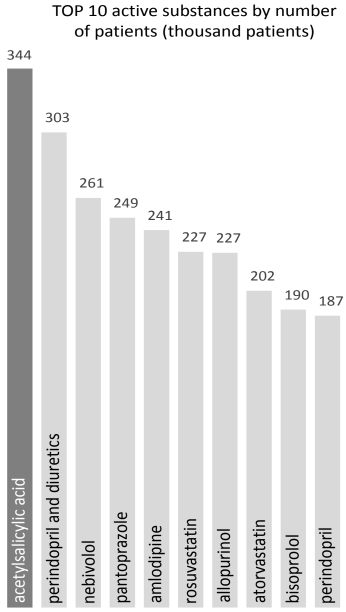


Source: Pharmacy turnover data, Healthware analysis

Average number of medical sales reps



Source: NHIFA data, Healthware analysis



Source: Pharmacy turnover data, Healthware analysis

Biosimilars in Europe and in Hungary – Case study

In our case study published in November 2016, we reviewed the European market of biosimilars, examining the biosimilars which were authorized by EMA (Europen Medicines Agency) and got reimbursed by NEAK (National Health Insurance Fund) till 2016 from different perspectives.

Reviewing the authorizations for the last two years, two things should be noted regarding the biosimilar market. Firstly, the activity in producing and accepting new biosimilars is significantly growing in Europe. Secondly, more and more original or generic firms with original parent company are participating in the production of biological medicines. The table below shows the biosimilar products available in Europe and reimbursed in Hungary (red type color shows the changes since 2016).

INN	Therapy area	Biosimilars authorized in Europe	Reimbursed biosimilars in Hungary
adalimumab	Rheumatoid Arthritis, Psoriatic Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriasis, Crohn Disease, Ulcerative Colitis, Hidradenitis Suppurativa, Uveitis	Amgevita, Cyltezo, Halimatoz, Hefiya, Imraldi, Solymbic	
bevacizumab	Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Colorectal Neoplasms, Fallopian Tube Neoplasms, Ovarian Neoplasms, Peritoneal Neoplasms	Mvasi	
enoxaparin sodium	Venous Thromboembolism	Inhixa, Thorinane	
epoetin alfa	Chronic Kidney Failure, Anemia, Cancer	Abseamed, Binocrit, Epoetin Alfa Hexal	Binocrit
epoetin zeta	Anemia, Autologous Blood Transfusion, Cancer, Chronic Kidney Failure	Retacrit, Silapo	Retacrit
etanercept	Rheumatoid Arthritis, Psoriatic Arthritis, Juvenile Rheumatoid Arthitis, Psoriasis, Ankylosing Spondylitis	Benepali, Erelzi	
filgrastim	Neutropenia, Cancer, Hematopoietic Stem Cell Transplantation, Mobilisation of peripheral blood progenitor cells (PBPC)	Accofil, Filgrastim Hexal, Grastofil, Nivestim, Ratiograstim, Tevagrastim, Zarzio	Accofil, Nivestim,Ratiograstim, Tevagrastim, Zarzio
follitropin alfa	Anovulation	Bemfola, Ovaleap	Bemfola
infliximab	Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Psoriasis, Crohn Disease, Ulcerative Colitis	Flixabi, Inflectra, Remsima, Zessly	Inflectra
insulin glargine	Diabetes Mellitus	Abasaglar, Lusduna, Semglee	Abasaglar
rituximab	Non-Hodgkin Leukemia, Chronic, B-Cell, Lymphocytic Leukemia, Wegener Granulomatosis and Microscopic Polyangiitis, Rheumatoid Arthritis	Blitzima, Ritemvia, Rituzena, Rixathon, Riximyo, Truxima	Truxima
somatropin	Turner Syndrome, Pituitary Dwarfism, Prader-Willi Syndrome	Omnitrope	Omnitrope
teriparatide	Osteoporosis	Movymia, Terrosa	
trastuzumab	Breast Neoplasms HER2+, Stomach Neoplasms HER2+	Herzuma, Kanjinti, Ontruzant	Herzuma

Until November 2016, twenty-three products got the marketing authorization in the EU. Currently (according to data from July 2018) this number is at forty-five, and these biosimilars are following therapies of fifteen substances (this means six new substances since our previous analysis). In the last two years, two biosimilar products (Truxima, Herzuma) got reimbursed in Hungary, giving a total of 13 financed biosimilars[1]. Examining the producers of the newly authorized biosimilars, we can observe that original or generic firms with original parent companies show greater activity than generic firms. The innovative firms placed thirteen biosimilars on the market in the last two years, while their generic competitors came up only with one new biologic medicinal product. Among the producers there is a growing number of firms focusing on biosimilars only, they had eight new product in this period.

Region	Number of brands (Number of brands 2016 November)	Type of producer: Innovative	Generic, subsidiary of innovative	Generic	Other
Region	Europe	2 (0)	14 (8)	8 (7)	
Region	North-America	6 (1)		1 (1)	1 (0)
Region	Middle-East			2 (2)	
Region	Asia				11 (4)

Number of brands (Number of brands, November 2016)

Similar to generics, the entry of biosimilars offers great opportunities on the social level. Their appearance ensures a savings potential for the drug budget and/or it can mean access to these therapies for a broader circle of patients. However, contrary to the generic products, there are many things which impedes the biosimilars' penetration and the realization of the above mentioned positive effects.

Firstly, in March 2018 an OGYÉI (National Institute of Pharmacy and Nutrition) resolution was published, according to which switching between different biosimilars of the same reference product (originator) is not recommended[2]. Although there was an example of good practice in the past for the interchangeability of biosimilars, the referred authority resolution might make the penetration of biosimilar medicinal products more complicated.

Secondly, one biosimilar product can be applied to many therapeutic indications - not necessarily from the same medical field. This makes the market entry and funding of these products more difficult since a biosimilar might have different patent expiry for the different indications. These patent right issues call the producers and the payer as well for caution.

Finally, we need to take into account, that the price reduction effect in case of biosimilar entry might not reach the extent of the same effect experienced in case of generic market entry. Not only the biosimilars' price sequence is slighter than generics'[3], but there is no need for producers to adjust to it since the level of competition is lower in the biosimilar market than it is in the generic market. Moreover, the price strategy of original producers – whose growing dominance on the biosimilar market we have already mentioned- fundamentally differs from that of generic producers. Therefore the realization of the expected price reduction and the savings effect arising from that is questionable in the case of biosimilars' market entry.

For its social benefits, it is definitely important to encourage the penetration of biosimilars and abolish the obstacles to it. Collecting real-world data about the application of biosimilar medicines, assembling it into registers, and analyzing them might be a primary tool to the solution. For example, the evaluation of data about switching therapies with properly controlled and documented circumstances could help to resolve the aversion related to the interchangeability of biosimilars. But the analysis of other information by identifying and separating patient subgroups could allow implementation of differentiated financing techniques.

[1] http://www.oep.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/pupha/Vegleges_PUPHA.html

[2] http://www.ogyei.gov.hu/dynamic/biohasonlo_allasfoglalas_20180212_Final_jav1_20180301.pdf

[3] http://njt.hu/cgi_bin/njt_doc.cgi?docid=84085.351867