HEALTHWARE

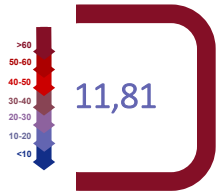
Actualities of Hungarian pharmaceutical financing market

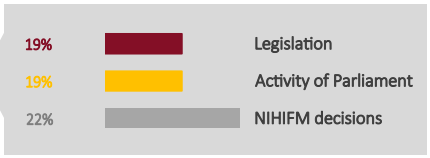
Newsletter
No. 4, Issue VII. 2019
Published: 18/04/2019

News, current issues

- News: 5 bold predictions for pharma »
- News: 70 innovative drugs waiting for reimbursment inclusion »
- News: Oncological diseases in the focus of pharmaceutical research »

Decision-making index, February 2019

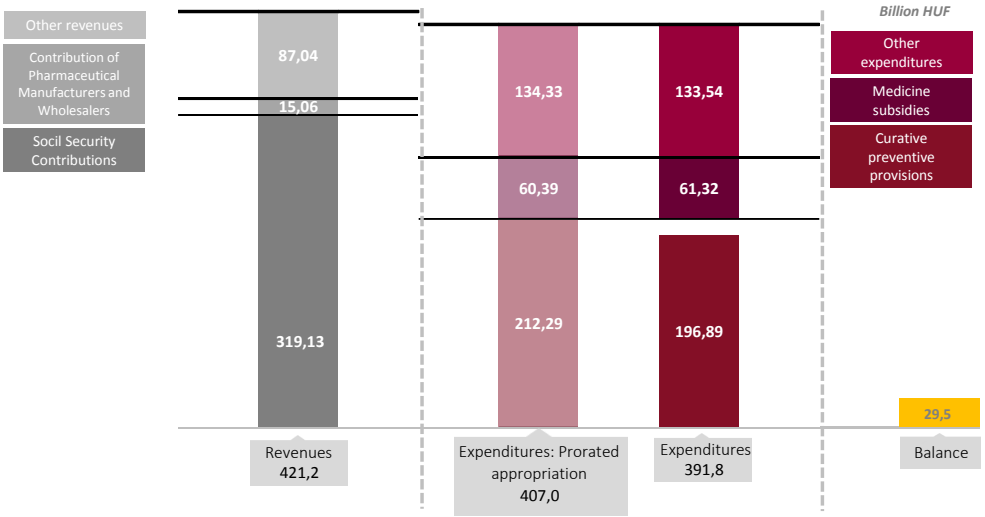




*Read more about our new methodology in our **previous case study.***

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund, February 2019



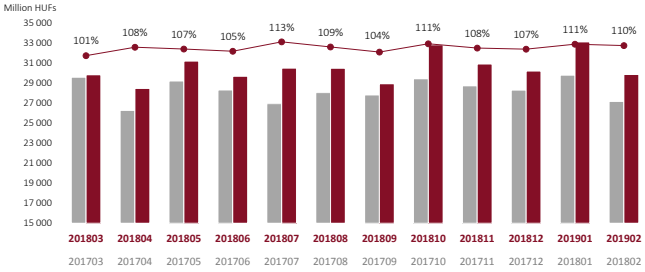
Source: Healthware analysis based on NHIFA data

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

Pharmacy DOT turnover

Source: Healthware analysis based on NHIFA data

Pharmacy reimbursement turnover



Source: Healthware analysis based on NHIFA data

Product

Revealing real symptoms of diseases

In the analysis basic country-wide demographic data related to diseases (prevalence, incidence, mortality rates) are summarized along with randomly chosen subcategories (area, sex, primary disease, accompanying diseases [comorbidity]).

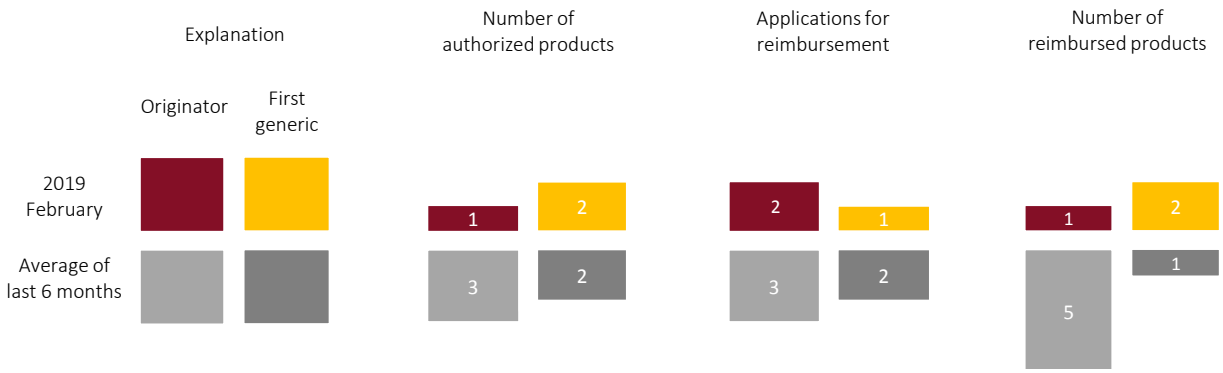
As a result of the analysis, the basic epidemiological characteristics of a given therapeutic area can be brought to light, which may provide a point to any further research, or may be suitable for independent use, especially in professional material to the attention of physicians.

Because there is no publicly accessible central patients' register, only limited disease-related data and information is available.

Consequently these pieces of information can play a valuable role on their own.

Further information: **link**

Changes to subsidized medicinal product categories, February 2019



Source: Healthware analysis based on NHIFA data

Healthware Consulting Ltd.
H-1093 Budapest Közraktár st. 30-32. 7th floor. I + 36-1-324-2050

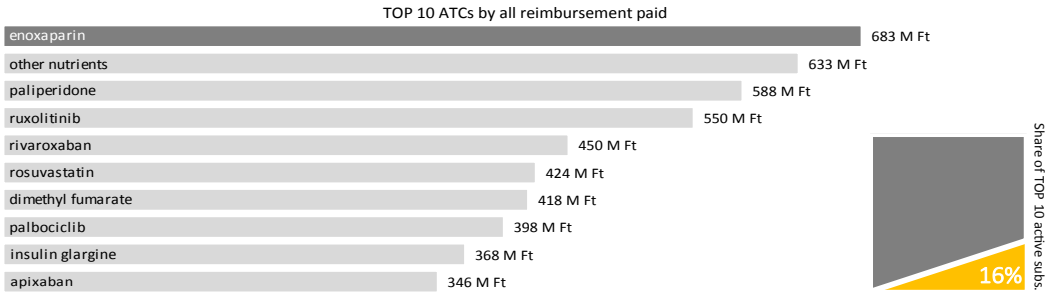
HEALTHWARE

Actualities of Hungarian pharmaceutical financing market

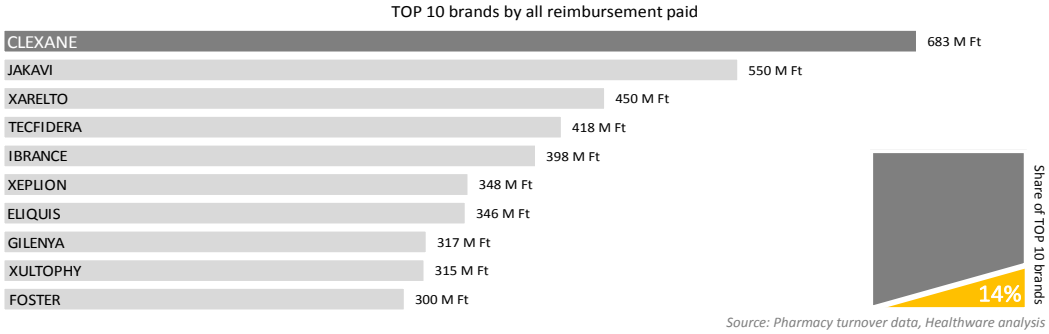
Newsletter
No. 4, Issue VII. 2019
Published: 18/04/2019

Market data

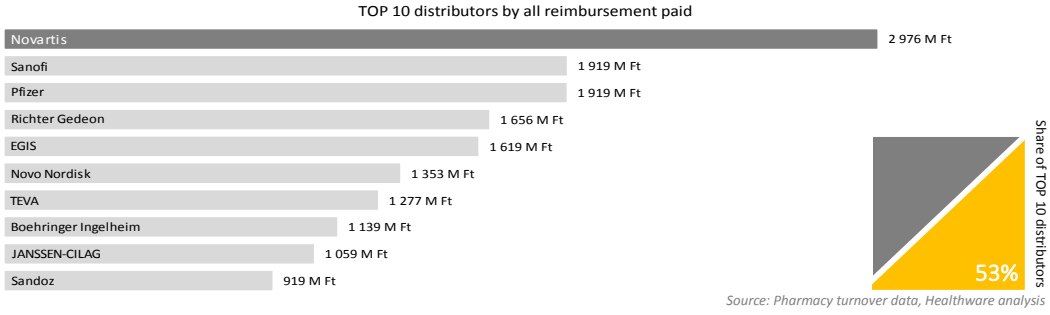
Toplists of reimbursement and number of patients, February 2019



Source: Pharmacy turnover data, Healthware analysis

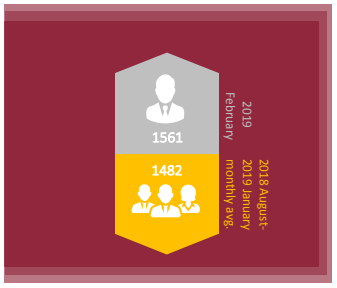


Source: Pharmacy turnover data, Healthware analysis

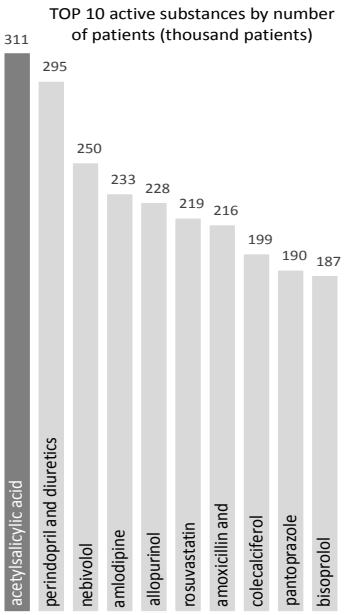


Source: Pharmacy turnover data, Healthware analysis

Average number of medical sales reps



Source: NHIFA data, Healthware analysis



Source: Pharmacy turnover data, Healthware analysis

Analysis of human medicines authorised by the European Medicines Agency (EMA) in 2018 — case study

BACKGROUND AND METHOD

The objective of our case study of April was to analyse those human medicines which have been authorised by the European Medicines Agency (EMA) in 2018. The analysis is based on published EMA data referring to authorised brands between 01/01/2018 and 31/12/2018.[1]

Extension of therapeutic indications of the brands, or changes in their summary of product characteristics or route of administration were not considered during this analysis.

RESULTS

Authorised brands and new substances in 2018

93 new brands were authorised by EMA in 2018 (same as in 2017) and 53 of it has a new active substance (increased value compared to 2017, when 35 new substance were authorised). In 2018 number of generic and biosimilar brands were 12 and 16, respectively. Most common biosimilar substances were adalimumab (25%), trastuzumab (25%) and pegfilgrastim (31%).

Authorised brands by ATC groups

The authorised brands cover a wide range of therapeutic areas, but a significant part of them provide a new solution of immunoncology. In addition to the breakdown of brands by ATC1, we also examined whether new ATC5 categories were generated within these groups to showing molecules that opened a new therapeutic area, see in Table 1.

Table 1. Authorised brands by ATC groups

ATC1	Number of brands in the given ATC1 group*	Number of brands with new ATC code in the given group**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS (ATC: L)	37 (40%)	5 (14%)
ANTIINFECTIVES FOR SYSTEMIC USE (ATC: J)	14 (15%)	–
ALIMENTARY TRACT AND METABOLISM (ATC: A)	11 (12%)	2 (18%)
NERVOUS SYSTEM (ATC: N)	9 (10%)	3 (33%)
BLOOD AND BLOOD FORMING ORGANS (ATC: B)	7 (8%)	–
RESPIRATORY SYSTEM (ATC: R)	5 (5%)	–
GENITO URINARY SYSTEM AND SEX HORMONES (ATC: G)	2 (2%)	1 (50%)
MUSCULO-SKELETAL SYSTEM (ATC: M)	2 (2%)	–
VARIOUS (ATC: V)	2 (2%)	–
SENSORY ORGANS (ATC: S)	2 (2%)	–
CARDIOVASCULAR SYSTEM (ATC: C)	1 (1%)	1 (100%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS (ATC: H)	1 (1%)	–

* With the rate of the brands considering all of the authorised brands in 2018.
** With the rate of the brands considering the number of brands in ATC1 group.

Distribution of brands by age

Of the authorised brands 62, 31 and 6 brands are indicated for adults, adults and children, and only for children, respectively. Pediatrics medicines are for the treatment of insomnia, diabetes mellitus, West-syndrome, adrenal insufficiency, severe vernal keratoconjunctivitis and X-linked hypophosphatemia.

Advanced-therapy medicinal products (ATMP)

There are also advanced-therapy medicinal products (ATMPs) among the products registered in 2018, including innovative therapies based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). The new preparations are anticancer agents and are the following: the first chimeric antigen receptor (CAR) T-cell therapies in the European Union which mean novel solution for the treatment of large B-cell lymphoma (DLBC) and B-cell acute lymphocytic leukemia (ALL) (Kymriah, Yescarta); a gene transfer vector that is indicated for the treatment of loss of vision due to hereditary retinal dystrophy caused by RPE65 mutations (Luxturna); as well as an injection of expanded adipocyte stem cells (eASC) for the treatment of complex perianal fistulae (Alofisel).

Figure 1. Advanced-therapy medicinal products (ATMP)

Luxturna
- Treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations

Kymriah
- Treatmen of paediatric and young adult patients with ALL
- Treatmen of adult patients with DLBCL

Yescarta
- Treatment of adult patients with DLBCL
- Treatment of adult patients with PMBCL

Alofisel
- Treatment of complex perianal fistulas in adult patients with nonactive/mildly active luminal Crohn's disease

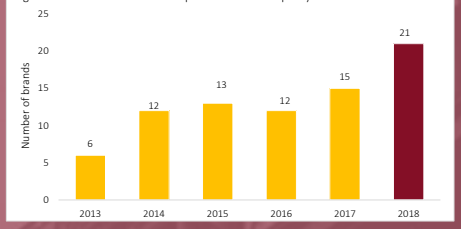
Medications for orphan diseases

21 of the 93 registered products are used for the treatment of orphan diseases (including the above-mentioned ATMP preparations), such as antineoplastic agents (24%), gastrointestinal and metabolic drugs (14%), nervous system drugs (10%) as well as a cardiac therapy (5%) and a respiratory system product (5%).

Analysis of human medicines authorised by the European Medicines Agency (EMA) in 2018 — case study

The number of registered products for orphan diseases has increased in recent years, and this trend is illustrated in the figure 2. The brands presented in this chapter are products with definitive orphan status and other narrow therapeutic areas, such as targeted therapies have not been analysed in this case.

Figure 2. Number of authorised orphan brands in the past years



Reimbursement applications in Hungary

We also examined whether there are among the products registered in 2018, for which a reimbursement application has already been started in Hungary. For this, we used the latest official List of Submitted Reimbursement Applications by the National Health Insurance Fund (NEAK) on 17th of April.[2] In case of 25 brands (27%) the Hungarian procedure started since the 2018 registration and in 15 cases (16%) positive decision were made (simplified procedure: 10 applications/brands, normal procedure: 5 applications/brands).

Currently, three of the authorized orphan products have submitted a reimbursement application, which are still on process (Figure 3).

Figure 3. Reimbursement proccesses in Hungary- orphan drugs

Alofisel
- Treatment of perianal fistulas in adult patients
- Itemized reimbursement category
- Still on process

Mylotarg
- Treatment of AML in patients over 15 years
- Itemized reimbursement category
- Still on process

Prevymis
- Treatment of CMV in adult patients
- 0%-Normative reimbursement category
- Still on process

From the newly authorized 53 active substances, the reimbursement application already had launched for 12, and in case of 4 brands positive decision have been already made, from which three products are for the treatment of type 2 diabetes in adults.

Figure 4. Reimbursed brands with new active substance in Hungary

Adynovi (rurioctocog alfa pegol)
- Treatment of haemophilia A in patients over 12 years
- Reimbursed from special budget
- Reimbursed from 01/10/2018

Ozempic (semaglutide)
- Treatment of type 2 diabetes in adults
- 70%-Indication based reimbursement category
- Reimbursed from 08/04/2019

Segluromet (ertugliflozin and metformin HCl)
- Treatment of type 2 diabetes in adults
- 70%-Indication based reimbursement category
- Reimbursed from 08/04/2019

Steglatro (ertugliflozin)
- Treatment of type 2 diabetes in adults
- 70%-Indication based reimbursement category
- Reimbursed from 08/04/2019

SUMMARY

A significant part of the EMA-registered products in 2018 expand the therapeutic potential of immuno-oncology. It is also evident that there is a progress in the treatment of rare diseases, and that the number of brands with orphan status shows a significant increase over the past years. In 2018, several biosimilar brands were registered as generics, and in a significant number of cases (63%) the application procedure was launched in a relatively short time in Hungary.

[1] EMA, European public assessment reports (17/04/2019) https://bit.ly/2EVIgI4
[2] NEAK, List of Submitted Reimbursement Applications (17/04/2019) https://bit.ly/2UIjYEH