HEALTHWARE

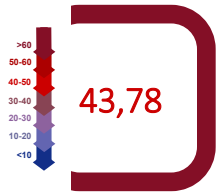
Actualities of Hungarian pharmaceutical financing market

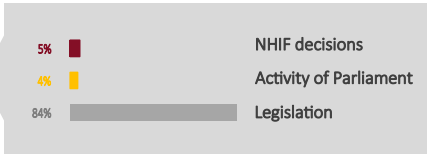
Newsletter
No. 4 Issue IX. 2021
Published: 04/23/2021

News, current issues

- News — New types and challanges in the primary care »
- News — Hospitals are unable to pay the suppliers »
- News — No such event in the last 9 months in pharmacies like in February »

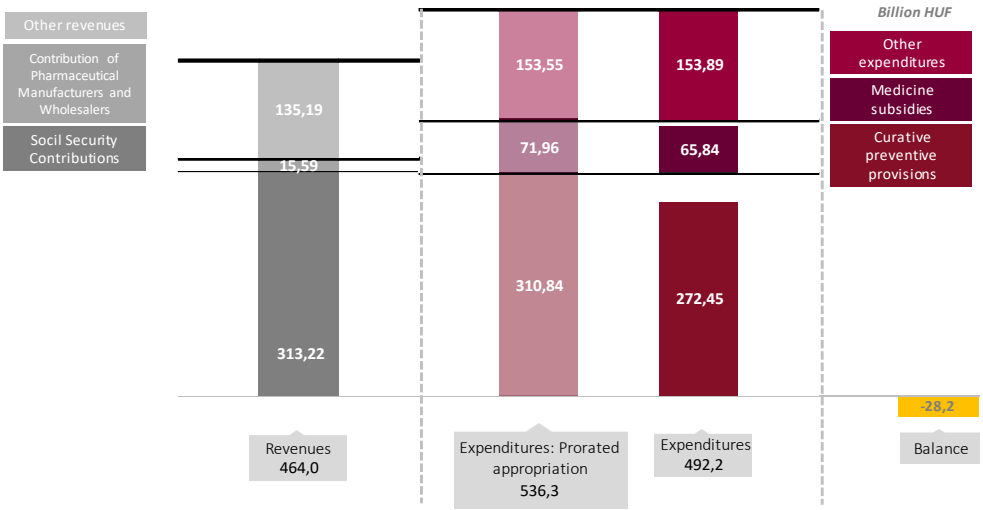
Decision-making index, February 2021





Macro approach to financing healthcare and medicinal products

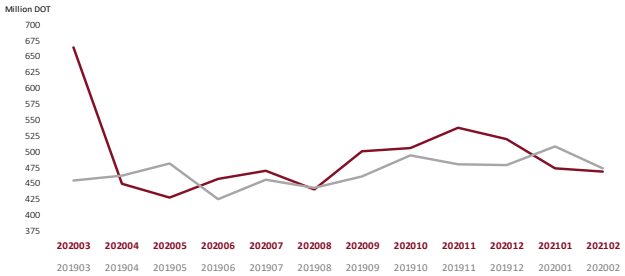
Balance of the Health Insurance Fund, February 2021



Source: Healthware analysis based on NHIFA data

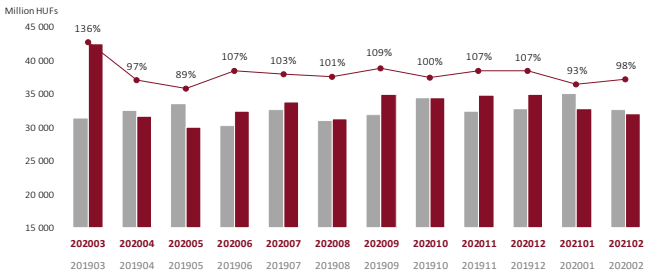
Dynamics of the sales/circulation of prescription-only-medicine

Pharmacy DOT turnover



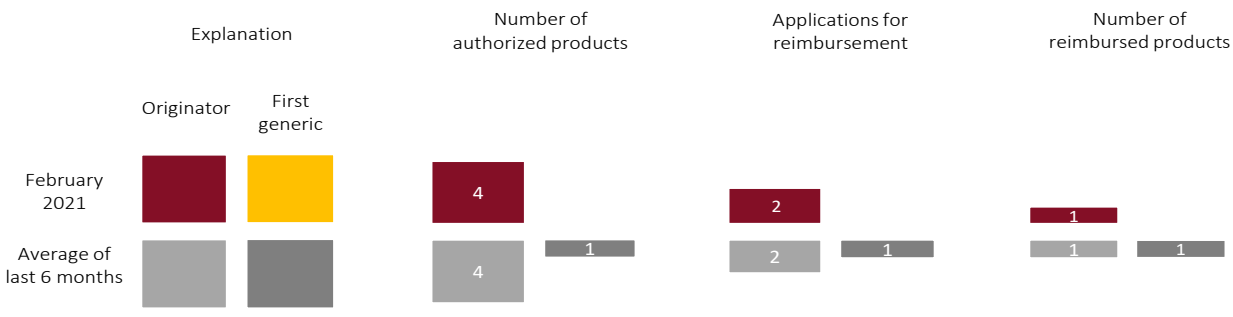
Source: Healthware analysis based on NHIFA data

Pharmacy reimbursement turnover



Source: Healthware analysis based on NHIFA data

Changes to subsidized medicinal product categories, February 2021



Source: Healthware analysis based on NHIFA data

Product offering

Burden of disease analysis

The indirect costs of therapies can currently be validated in only a limited way in health economic analysis made from local financing viewpoint. However, in other levels of decision making the cost analyses, which are made in social approach, can include objective and well communi-cable messages. These details can aid in forming of preferences between different healthcare technologies. By way of data-request from OEP we provide the sum-ming up of the following information:

- Demographic and epidemiologic characteris -tics (by age, sex and comorbodity)
- Dispersion of patients by disease severity based on pharm. treatment pattern
- Cost analyses (on data of prescr., inpatient and outpatient care, labs and diagnostic services, hospice, sickness benefit)

We suggest the patient survey method to define the patients indirect costs and the other state expenditure

- Sickness absence costs
- Home remodeling costs
- Informal care
- Other indirect burdens

More information about our services: **link**

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

Subscribe Unsubscribe

HEALTHWARE

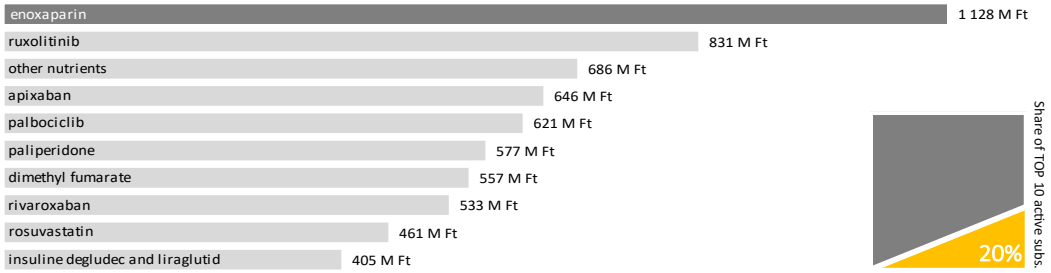
Actualities of Hungarian pharmaceutical financing market

Newsletter
No. 4 Issue IX. 2021
Published: 04/23/2021

Market data

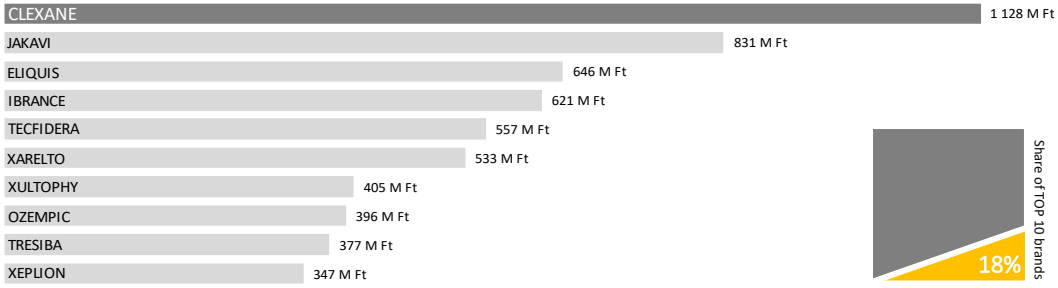
Toplists of reimbursement and number of patients, February 2021

TOP 10 ATCs by all reimbursement paid



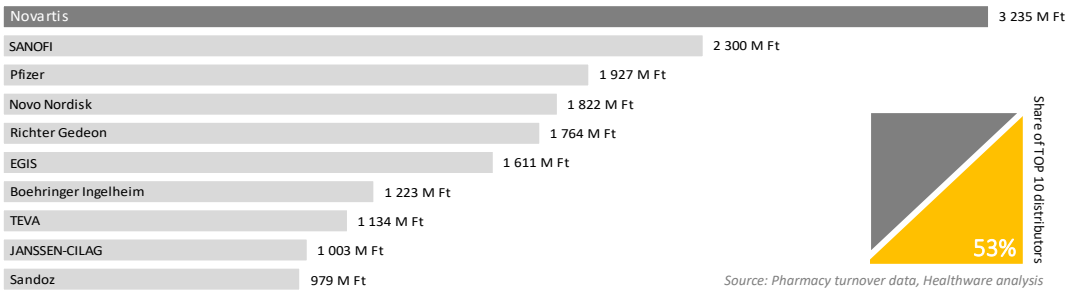
Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



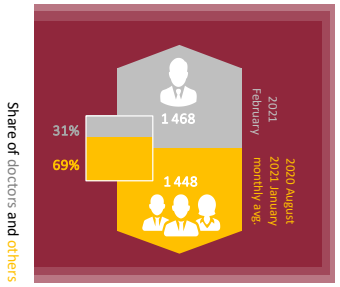
Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



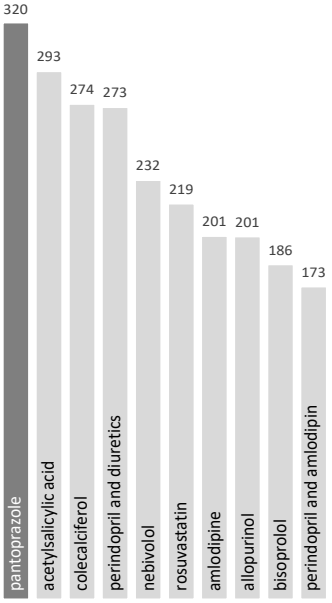
Source: Pharmacy turnover data, Healthware analysis

Average number of medical sales reps



Source: NHIFA data, Healthware analysis

TOP 10 active substances by number of patients (thousand patients)



Source: Pharmacy turnover data, Healthware analysis

Reimbursement and submission procedure of medical aids — Case study

Healthware analysis based on NEAK data

In our case studies, we regularly analyse reimbursement applications of medicines and the public data from these procedures; at the end of 2020, within a separate case study we examined the inclusion of health technologies into the healthcare system. In this present case study we would like to provide an insight into the field of Medical Aids.

Based on the corresponding legislation, medical aids are a group of the medical technology devices, which can be defined as follows[1]:

„Any medical device made available for personal use to patients suffering in a temporary or persistent health impairment or disability (including in vitro diagnostic medical devices for self-testing purposes), and other technical devices for nursing and caring purposes, which are not treated as medical devices, designed for use without the continued presence of a healthcare professional. Personal use shall mean where the medical aid is worn, applied or administered in body cavities with exterior opening, whether natural or artificial, or on the body, including the use of in vitro diagnostic medical devices for self-testing purposes on specimens derived from the human body, and the use of equipment for supporting or moving the body for diagnostics purposes or for the purpose of therapy, rehabilitation or nursing."

REIMBURSEMENT ENVIRONMENT

The reimbursement of medical aids appears in the budget chapter of the National Health Insurance Fund, the budgete appropriation for 2021 is HUF 80 billion.

In the annual amount of the medical aids budget, an annual 6-10% increase can be seen in recent years. However, based on our experiences, manufacturers and distributors report difficulties and pricing problems regarding obtaining reimbursement. Considering public data, we started to analyse healthcare reimbursement applications, produres and decisions, in order to identify the background of this increase in expenditures: the inclusion of new products/product groups or changes in the price/reimbursement of already reimbursed products.

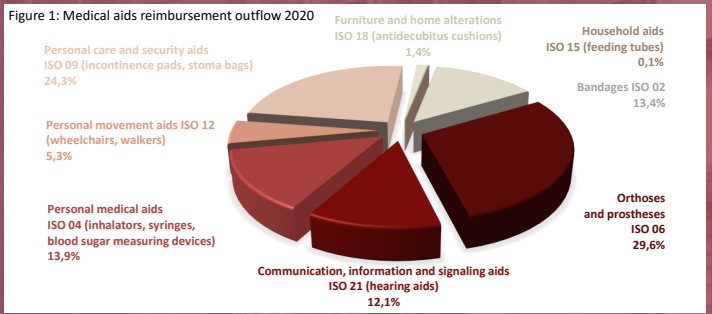
[1]*Gyftv, Act XCVIII of 2006*

To understand this analysis, a few basic information should be highlighted first:

- The reimbursement applications considering medical aids are regulated by the Gyftv. (Act XCVIII of 2006), the 451/2017 Government Decree, and the 14/2007 EüM Decree.
- In the reimbursement and inclusion of medical aids, several principles are taken into account, according to the legislation, however, decisions are mainly price-oriented.
- For the reimbursement application of medical aids, a so-called NEOEMKI certificate is required. This certificate includes a description of the device (e.g. details of the technical parameters), proposes an ISO code classification, and also contains the basic characteristics of the device in a summarised and understandable manner, in Hungarian.
- Normal and accelerated applications undergo a full evaluation (technology assessment, involvement of a professional college).
- Fixation takes place every six months, following the appropriate fixation rules.

The figure below shows the composition of reimbursement outflow on medical aids: the largest reimbursement outflow in 2020 appeared in the group of orthoses and prostheses, followed by the devices of personal care and security aids (incontinence pads, stoma bags); these two large groups accounts for more than half of the budget.

Figure 1: Medical aids reimbursement outflow 2020



Reimbursement and submission procedure of medical aids — Case study

Healthware analysis based on NEAK data

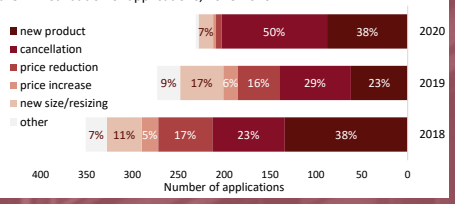
ANALYSIS OF REIMBURSEMENT APPLICATIONS

Within the framework of this analysis, we examined transparently available information regarding the reimbursement applications of medical aids, their initiation and the decisions made, based on the data of the past 3 years. Based on NEAK public data, reimbursement applications of medical aids were divided into 6 groups, groups with small sample size were classified into an 'Other' category:

- new product
- new size/resizing
- price increase
- price reduction
- cancellation
- other (change of name, determination of daily rental fee, reduction of daily rental fee, classification into other functional group, ex officio procedure)

Figure 2. shows the distribution of these procedural categories among the medical aids applications, for the period of 2018-2020.

Figure 2: Distribution of applications, 2018-2020



Based on data from the past 3 years, the following findings can be made:

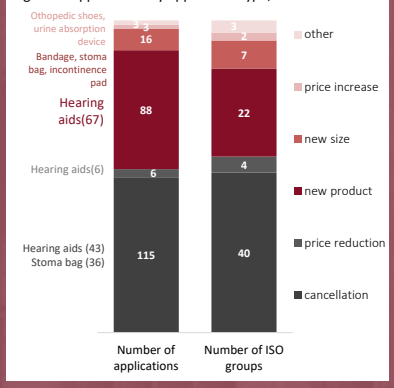
- In all of the three years, the majority of the reimbursement applications was submitted for cancellation and regarding new products (in each year, 61%, 51%, and 88% of the applications was submitted due these reasons, respectively). We can assume that products are deleted in accordance with their life cycle; the reimbursement of an older device/type/version is deleted, then the newer version appears as an application for a new product.
- In 2018-19 a high number of applications were submitted due to price reduction and change in size; applications regarding price increases are also present to a smaller extent.
- The number of submitted price increase applications is not significant (2018: 18; 2019: 16; 2020: 3) and within these applications, only 2/3 of these applications ended with a positive decision (orthosis systems, urine absorption devices, impregnated gauze sheets, orthopedic shoes).
- The majority of deletion, new product, and price decrease applications (in the case of price decrease applications, more than 90% of the applications) concerns hearing aids. The majority of resizing applications concerns catheters, incontinence devices and stomatotherapy devices.

Based on all of these, we can say that the majority of the submitted applications and the corresponding procedures concerns a smaller segment: hearing aids, incontitence pads, and stoma bags.

Most of the involved ISO groups occur in hearing aids (ISO 21 45), for which the reimbursement turnover are extremely high; the size of the reimbursement paid on these devices exceeded HUF 7 billion in 2020, on an annual basis (which accounts for roughly one tenth of the medical aid reimbursement).

The dynamics in the number of applications suggests a correlation with the turnover when examined within hearing aids; in 2020, 54,5% of new product applications and 60,5% of cancellations concerned devices belonging to the group of behind-the-ear hearing aids.

Figure 3: Applications by application type, 2020



PROCEDURAL BUREAUCRATIC ELEMENTS

Transparency in the procedures for reimbursement applications concerning medical aids is similar to that regarding medicines, which is also regulated by the Gyftv. Depending on the procedure type, there are three types of procedural deadline for assessing medical aids applications; 90 days in the case of the normal procedure, for all application types, which is mainly the reimbursement of a new device, the determination of the rental fee, or price increase. The accelerated procedure is 60 days long, which is mainly possible for a new device, if the new product could enter the market on a 10% lower price than the cheapest product in the group (possible clinical trial). The 30-day simplified procedure applies for applications of already reimbursed medical aids due to renaming or resizing.

Similar to medicines, there are applications for medical aids which require change in legislation. If the NEAK receives an application regarding the inclusion of a new medical aid, for which the 14/2007. (III.14.) EüM Decree does not contain a functional group (subgroup) and the extent of reimbursement within that group, the NEAK suspends the procedure until the change in the legislation entries into force, for a maximum of 210 days calculated from the receipt of the application or the fulfillment of the deficiencies. If the legislation is not amended, the application must be assessed – rejected – after 210 days on the basis of the legislation in force (Gyftv. 34§ (2)).
According to the data of the National Legislation, Annex 10 of the above-mentioned Decree is amended once or twice a year, most recently in April 2020.

Based on the public data, in 2018 4, in 2019 2, and in 2020 7 medical aid application were received, in which cases the procedure was suspended for 210 days, presumably because they concerned a product, for which a new functional group was requested. Only a fraction of these procedures, 3 application ended with inclusion (insulin pump transmitter, sensor used in monitoring sugar level), and the time until positive decision was 336 days. For those applications ending by termination, the reason of the decision cannot be seen publicly (e.g. there was no legislation amendment during the time of the procedure).

CONCLUSION

Under the current reimbursement system for those medical aids which want to be included in a functional group given along the already reimbursed prices and gain reimbursement, the reimbursement application practically means a fulfillment of administrative requirements; the legislation does not provide substantive room for maneuver in the reimbursed price, compared to the already reimbursed products. Despite the above, the procedural service-administration fee is still high (700 000 HUF) and the procedure is burdened with an unnecessary technology assessment process (the mandatory required NEOEMKI certificate is a suitable basis for the cognition of the medical background of the device; the potential price of the device can vary within the legal framework).

For those medical aids, which are 'significantly' different from currently reimbursed products (where entering into another functional group and evaluating the cost-effectiveness during the technology assessment would be indeed justifiable), the procedure is tied to a legislature amendment. Given the low number of such applications, it apperas that manufacturers tipically do dot initiate such proceedings, or if they do so, the applications do not end succesfully. Consequently, due to its inertia, the process cannot support this form of innovation. Hence, the budget increase is not due to the appearance of such products.

Based on the analysis of the procedures, there are device groups, where the apperance of new products is continuous, however, these do not generate a reimbursement surplus due to the reimbursement rules (fixed reimbursement groups).

Price increases appeared only in a small number of applications (in 2020, more, with the exception of customised orthopedic shoes), hence this cannot be the reason behind the budget growth.
In the case of medical aids, the price construction of devices is very different from that of medicines (in the price of medical aids, labour costs represent a higher proportion; the price level and price structure of mass-produced and customised products are also completely different); the life cycle of the devices and the nature of innovation is not comparable to the medicines' life cycle and the innovation in the pharmaceutical industry, which factors are worth mentioning when discussing prices, inclusion and innovation.

RECOMMENDATIONS

The transparency is adequate regarding medical aids, however, the reimbursement environment and the rules are very bureaucratic, and the inclusion rules can only support few forms of innovation in their current form.

In formulating our proposals, the present analysis confirmed our previous experiences:

- It would be appropriate to reduce administrative requirements for reimbursement applications for medical aids (simplification of the list of attachments, electronisation of paper-based administration).
- The abolition of legislation amendment requirements considering inclusion in the event of opening a new functional group, which could make a significant contribution to innovation.
- In addition to the current role of NEOEMKI, the role of TÉF needs to be reconsidered, because the price-based inclusion does not require technology assessment, and the technology assessment made with medical-pharmaceutical background might not provide an adequate background for possible technical assessment. This requires a change that which types of applications may require a full evaluation (HTA).
- The above-mentioned recommendations could be accompanied by a possible reduction in service-administration fees.

In our view, it would be worthwhile to improve the current inclusion procedures, in order to ensure that innovative devices beyond currently reimbursed medical aid groups and price regulation issues are indeed available for Hungarian patients.