HEALTHWARE

Actualities of Hungarian pharmaceutical financing market

Newsletter
No. 3 Issue IX. 2021
Published: 03/30/2021

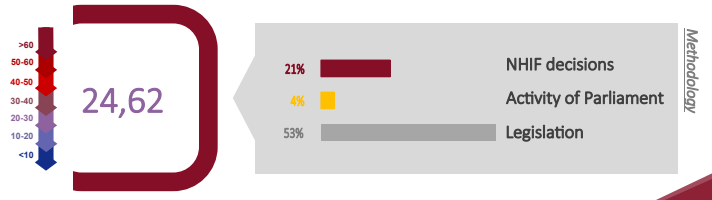
News, current issues

News — An investigation has been initiated against the pharmaceutical wholesalers by the Hungarian Competition Authority »

News — "Healthy Hungary 2021–2027" Sectoral strategy for the next seven years has been completed »

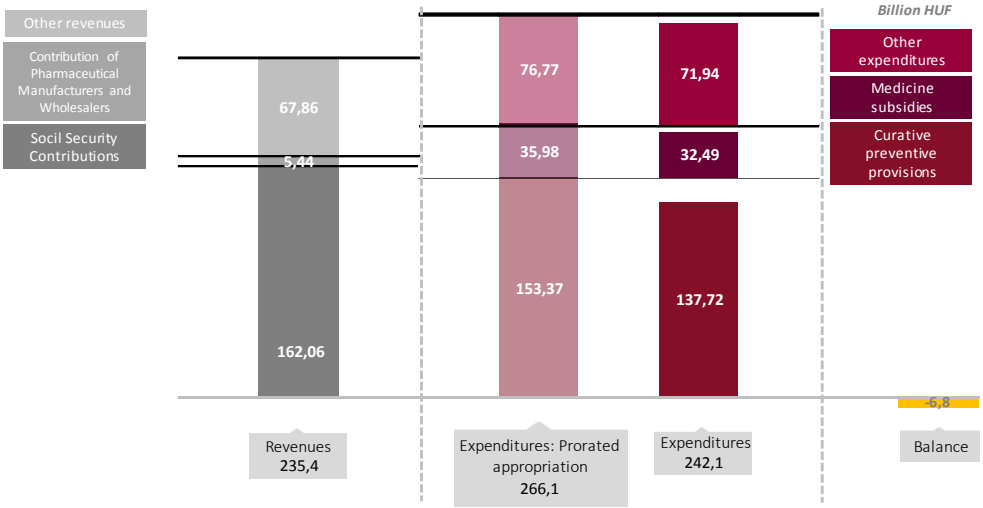
News — EESZT is becoming more and more relevant during the Covid-19 epidemic »

Decision-making index, January 2021



Macro approach to financing healthcare and medicinal products

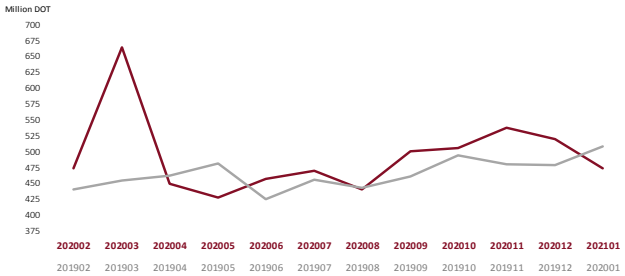
Balance of the Health Insurance Fund, January 2021



Source: Healthware analysis based on NHIFA data

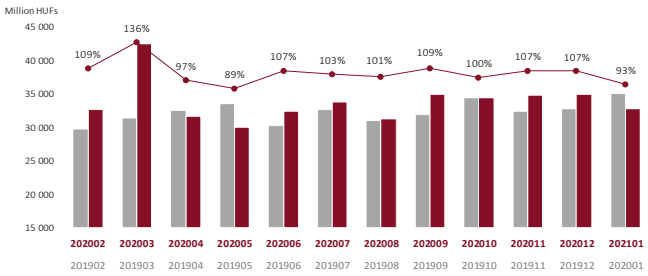
Dynamics of the sales/circulation of prescription-only-medicine

Pharmacy DOT turnover



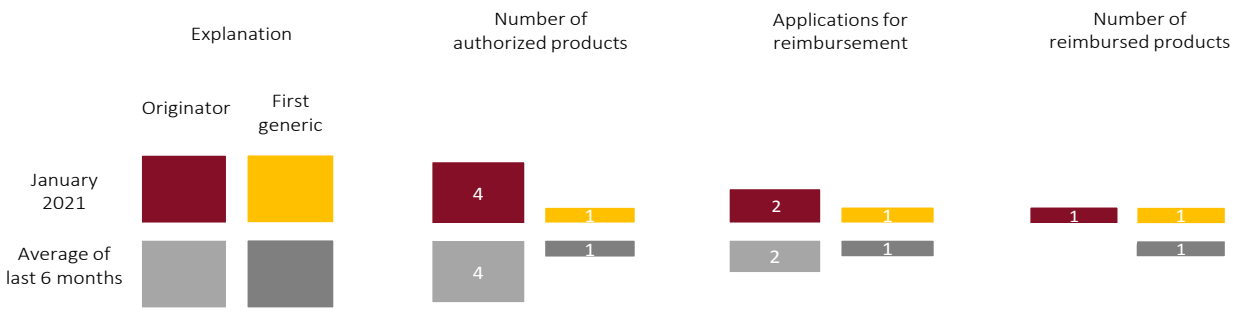
Source: Healthware analysis based on NHIFA data

Pharmacy reimbursement turnover



Source: Healthware analysis based on NHIFA data

Changes to subsidized medicinal product categories, January 2021



Source: Healthware analysis based on NHIFA data

Product offering

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**

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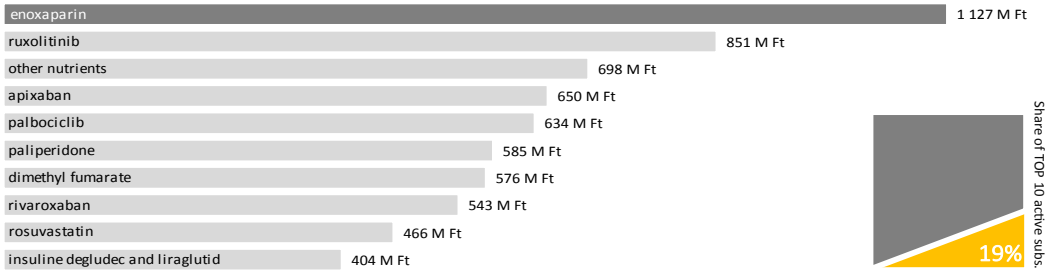
Market data

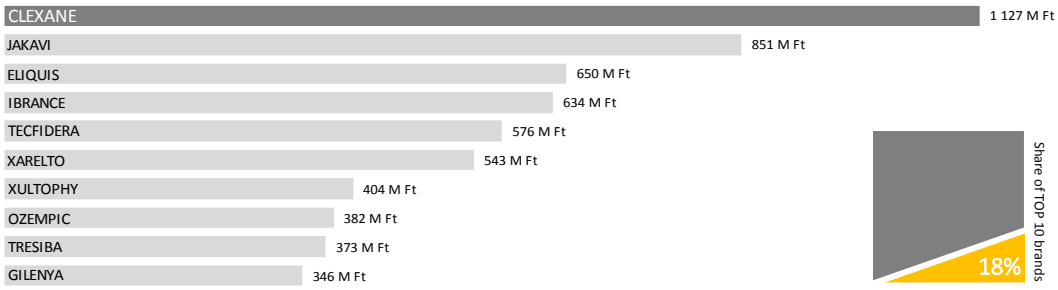
Toplists of reimbursement and number of patients, January 2021

TOP 10 ATCs by all reimbursement paid



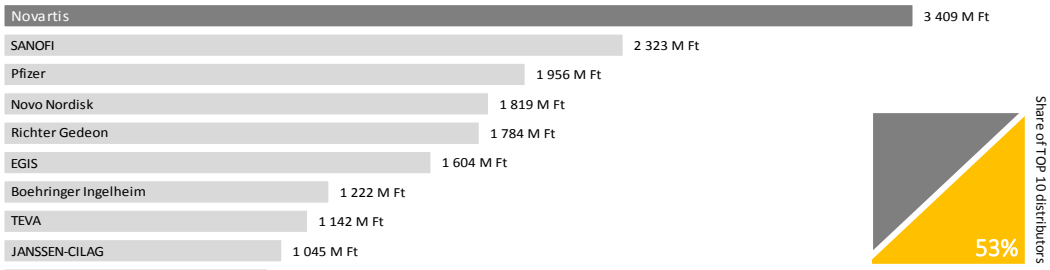
Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



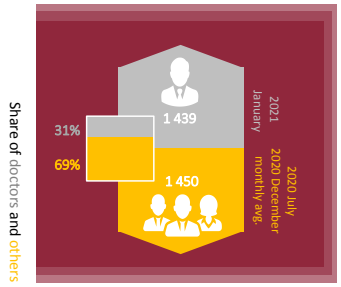
Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



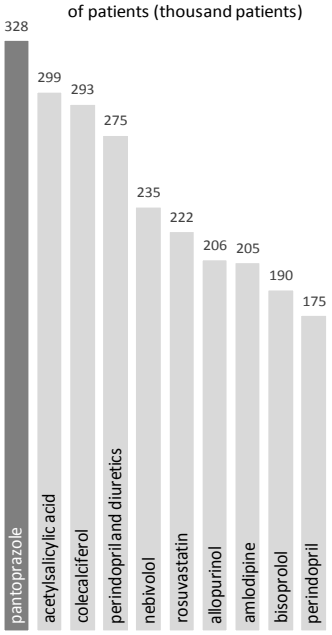
Source: Pharmacy turnover data, Healthware analysis

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

Analysis of Price-Volume Agreements (Part II) — Case study

Healthware analysis based on NEAK data

In our last case study, we examined the trends in certain conditions of price-volume agreements (hereinafter: PVAs), which may provide a picture of the funder's aspirations. Contract length and payment types were highlighted in this analysis.

Two main directions have been outlined:

- shortening of contract periods can be observed in recent years – reflecting the tendency of the NHIF (NEAK) to reconsider contracts more frequently–,
- no change can be observed in the proportion of payment types, box fee-based clawback type is still predominant (92% of the products have a box fee contract) which is merged by another payment type in half (53%) of these cases

This proportion of box-fee products calls into question the aim of PVAs to enable the less predictable new or high-value therapies to be provided for patients with modern funding tools while keeping the Health Fund under control. PVAs in this manner are not about risk management, but about a simple discount, which predicts the long-term maintenance of this contracting practice.

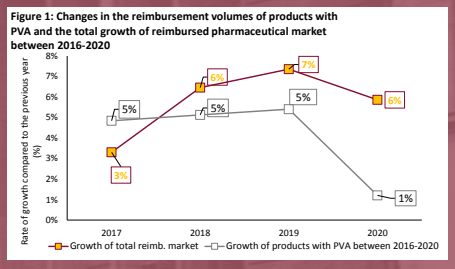
In this case study, we dig deeper into the topic, highlighting 3 more questions:

1. Is it really possible to limit the turnover of products with PVAs? Does the growth trajectories support this assumption?
2. How concentrated is the generated reimbursement outflow of the products with PVA? Do we see correlations in the allocation of contract types?
3. What may be the criteria for leaving PVAs?

PVA PRODUCTS VS OVERALL PHARMACEUTICAL MARKET — GROWTH TREND

As the first step, it was analyzed on a yearly basis whether the PVAs could be considered as real barriers in the product turnover. For this purpose, - based on the public lists - we selected the brands under continuous PVA contracts between 2016 and 2020, with already existing turnover before 2016. The turnover and growth of this product scope have been illustrated in Figure 1, compared to the turnover and growth of the whole pharmaceutical market. In the comparison, we can see that, except for the first year, the growth rate of the products covered by contract did indeed remain below the total pharmaceutical market throughout the period considered. The growth of the products concerned is around 5% between 2017-2019, while in 2020 (when their PVA contracts have been in force for at least 5 years), the product scope shows only 1% growth.

Figure 1: Changes in the reimbursement volumes of products with PVA and the total growth of reimbursed pharmaceutical market between 2016-2020



However, if we include the products with PVA that had a reimbursement turnover for the first time in 2016 – the PVA products will far exceed the total growth of the pharmaceutical market, but in the case of the pharmaceuticals being in the early stages of their product life cycle the 5-7% increasing trend is not surprising.

The growth of the brands having contracts between 2016-2020 was also examined separately, grouped according to the rate of growth. Figure 2 shows the development of the size of the groups formed according to their average annual growth rate in the examined years (2017-2020) and their typical growth rate in 2020.

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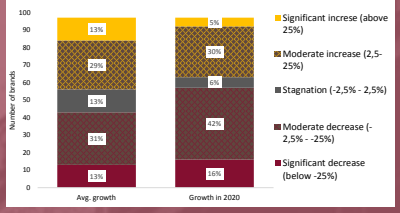
Throughout the period under investigation, the brands generating an increasing, decreasing, or stagnant reimbursement turnover were relatively evenly distributed among the products covered by the PVA. Especially in the last year, however, this balance was upset. The proportion of brands with declining turnover increased above 50%, while the proportion of stagnant and growing brands decreased (from 55% to 41%).

Figure 2: Classification of products with PVA throughout 2016-2020 based on the increase in reimb.turnover

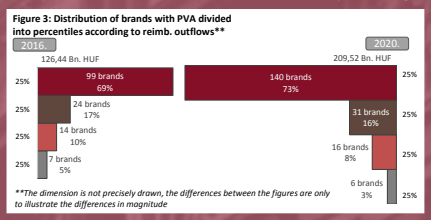


Based on the data, it can be stated that after five years under PVA, the proportion of declining brands show a slight increase, but even after five years, a relatively significant number of brands are able to achieve growth in the reimbursement outflow.

CONCENTRATION OF BRANDS WITHIN THE PVA RELAT,ED REIMBURSEMENT OUTFLOW

Our second question concerned the concentration of brands. A quarter of the total 2020 reimbursement outflow of the 2020's PVA product group was generated by a total of 6 brands, while another 140 brands - with the lowest reimb. turnover - were needed in order to generate the same costs for NEAK. We see a similar pattern in the 2016 list, where 32% of brands had the 75% of the reimb. outflow (27% in the 2020 list).

Figure 3: Distribution of brands with PVA divided into percentiles according to reimb. outflows**



**The dimension is not precisely drawn, the differences between the figures are only to illustrate the differences in magnitude

According to the current practice of contracting PVAs, the expected reimb. outflow has not yet been an inclusion criterion; hence it can be considered as natural that not only the products with a higher turnover are included in the contracts. However, it is interesting whether we see any distinction between brands of greater or lesser turnover mass. In the case of products with a higher reimbursement value or a higher expected turnover, the question arises how the funder can control the costs, so in these cases, stricter types of payments - based on thresholds and performance - may be more common. However, we do not see this in the public contract lists. In 2020, 7 of the 20 brands with the largest outflow had only box fee payment obligations – which, while representing an extra cost to the distributor, is still an unsuitable tool for reimb. outflow limitation - while in the remaining 13 cases cap payment method is used (in one case independently, in 12 cases added to the box fee). Nevertheless, it is important to emphasize, that among the 20 brands, we do not see outcome-based contracts, ones that are able to determine the rate of clawback based on the effectiveness of therapies – with real clinical endpoints.

Thus, in addition to the fact that the higher-cost-generating pharmaceuticals are in a definite minority among the contracted brands, we can also see that there are surprisingly large numbers of simple contract types without restrictive incentives among them, which is suitable for reducing the level of (reimbursement) expenditure, but overall does not limit the increase in turnover.

CHARACTERISTICS OF BRANDS LEAVING PVA

Our third question related to PVA contracts is what may be the reason behind the departure of brands from the contracts, what proportion of this occurs automatically or naturally, and how many cases we see other explanation behind the departure.

Figure 4: Annual number of brands leaving the PVA

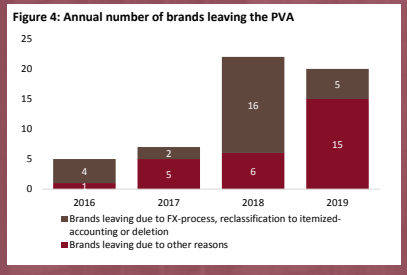
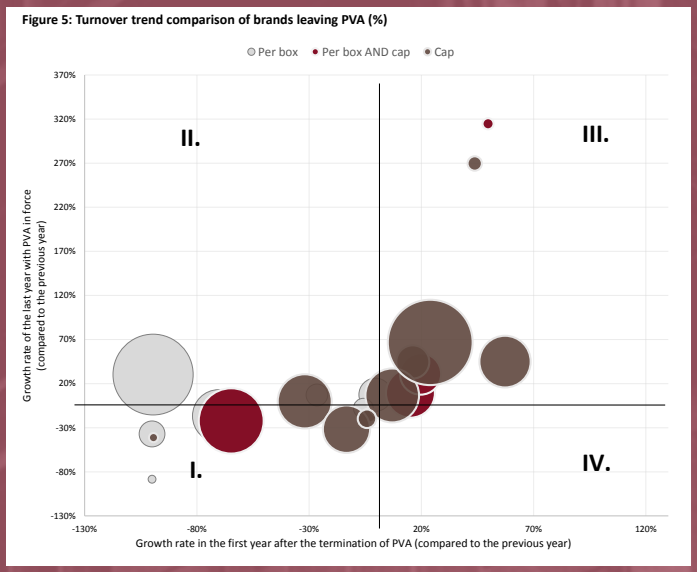


Figure 4 shows the number of brands leaving between 2016 and 2020 in annual breakdown; the products that appeared for the last time on the public list in the year indicated. Among them, those brands were separately differentiated that left the PVAs for a reasonable reason. (FX procedure, itemized- accounting, or being excluded from the reimbursed - or in some cases the total - market of the pharmaceutical market). Although their proportion varies from year to year, it is certainly interesting to note that there is a significant number of cases where it is not clearly defined how the product could 'get out' of the contract.

In the case of these products, we examined the development of their reimb. turnover by plotting the growth rate of their last year of PVA presence (last PVA year turnover compared to the one's before) and the growth rate of the following year – after the contract termination. The results are presented in Figure 5.

The 4 quarters of the figure are marked with a Roman numeral in order to provide guidance. The turnover of brands located in quarter I. showed a decreasing trend both before and after the dropout. In the case of these brands, it is in fact unjustified to maintain the PVA, given that their

Figure 5: Turnover trend comparison of brands leaving PVA (%)



turnover is predictable or even downright declining, hence they do not pose a threat to the health budget. Products in quarter II. can be similarly evaluated. Although before the dropout they showed an increase compared to the previous year, but their turnover decreased in the year when they no longer had contract. Among the brands leaving the PVA, the share of the reimbursement turnover is 49% for these quarters (I-II.), while the remaining 51% of the share is concentrated to quarter III. An increase in the volume of reimbursement in that year when the contracts had become terminated can still be observable in the case of brands plotted on quarter III., meaning that NEAK has released these products from the restrictive repayment terms despite the fact, that their turnover was still rising. Among them, two brands showed outstanding growth in reimbursement volumes (270%; 315%) in the last year of their contract and then grew by more consolidated around 50% after exiting - however, their extremely small market size (HUF 27 million of reimb. outflow/year leaving the PVA; HUF 16 million of reimb. outflow/year leaving the PVA) could be the reason to be released. However, in 9 more cases we find that with significant growth and market size, some brands could also leave the PVAs.

In the recent 2020 list, we find 71 brands that also show an increasing trend as early as 2019 and were able to continue to grow in 2020. Among them, however, there are also 5 brands, whose turnover in 2020 did not reach the outflow rate of HUF 50 million. Although no outcome-based repayment condition can be seen exclusively for any of these 71 brands, but in the case of 3 brands, the outcome-based condition appears merged with a box-fee AND cap or only box-fee repayment type. The question for the next period is whether these brands will remain under similar conditions or – like we have seen in the previous dropouts –, will be released by the Funder.

Thus, further examining the trend of leaving brands, it could have been reasonable to release the products of the quarter I-II. in the year concerned, but it must be taken into account that the termination of the PVAs with box-fee – designated on the figure with red color, and grey color in the case of the PVAs with box-fee AND cap condition – is practically equivalent to a price increase from NEAK's perspective. Despite the declining trend, these products still generate significant reimb. outflows, so releasing them means also cost to the Funder. Among the products of the quarter III-IV, in addition to cap contracts, we also find box-fee AND cap PVAs - albeit with a lower extent of reimb. outflow. In the case of these products, the question is even more relevant, how could they have left the scope of the contract.

We have seen several cases over the last 5 years where brands have left behind these contracts not because of automation or due to regulation. There is no specific reason behind some of the decisions but examining the turnover trends another part (in 42% of the examined cases – products in quarter I. of the decisions seem rational from the point of view of the financier.

However, if this is a decisive factor for the funder, about 22% of the brands on the public list in 2020 could be released in 2021 from the PVA framework - only considering this point of view. (This is the proportion of those brands that had declining reimbursement turnover in 2019 and 2020 as well, and their publicly available contracts with NEAK expired by 31 December 2020.) However, if we look only at the products with cap PVA - since in their case the reasonable goal is to limit the radical surge in turnover - there are still 4 expiring contracts for which it seems unjustified to conclude again in 2021 unless the repayment type is will not be changed to box fee.

Continued on the next page...

Analysis of Price-Volume Agreements (Part II) — Case study

Healthware analysis based on NEAK data

Overall, we can say that...

... the range of products included in the long-term PVAs is performing below the total market growth when considering the reimbursement turnover. The system can be considered effective from a purely fiscal point of view, as it manages to exercise control and reduce the volume of the brands with PVAs. However, the question is to what extent this subdued growth potential meets real utilization needs.

... The concentration of the brands involved is striking; 75% of the reimbursement outflows generated by the products on the 2020 list are due to 27% of all brands. Nevertheless, the cap contracts - which can indeed limit the outflow - are still not the primarily applied contract types -not even for the largest brands. We believe that an outcome-based approach should be applied for those products with a real breakthrough in innovation, and having a less predictable patient circle - so the lack of a valid cap can be justified. However, currently, this practice is very rare, even for brands with the highest reimb. outflow.

... Among the brands that were excluded from the PVAs between 2016 and 2020, there is a significant number of those for whom we do not see a clear reason (like FX process, classification into itemized accounting) to leave. However, the turnover trend of these brands is also heterogeneous - 42% of cases showed a decreasing trend in the year of the last PVA and subsequently, another 42% showed an increasing trend upwards. The former criterion - declining turnover - could be used as a definite decision point when re-concluding or terminating the contracts, while the latter -the increasing trend -, raises further questions. What can justify the release of these products from PVA if they still place an increasing burden on the funder with their marked increase in turnover?

Going further, we have not been able to identify a clear pattern based on size, which would support that it is easier for the funder to release the renegotiation of contracts below a certain market size.

PVAs fulfill their basic fiscal function and can provide significant financial control to NEAK. Nevertheless, it raises serious issues how rational or rather intuitive the prevailing aspects are when concluding / re-concluding a contract. Rationality is also difficult to see in the range of released products.

The maintenance and management of these contract negotiations is an increasingly important responsibility that requires very serious capacity and expertise of NEAK. In addition to the presented financial parameters, the special characteristics of the therapeutic area, the range and dynamics of the reimbursed drugs available in there, and the extent of the health gain achievable are also fundamental aspects. In the case of such a large volume, it may be worthwhile to develop internal decision support criteria, which determine the direction of decision-making in proportion to the fiscal and professional risks arose with the contracts. If these criteria have been already developed, sharing them with the public could further increase the transparency of PVAs.