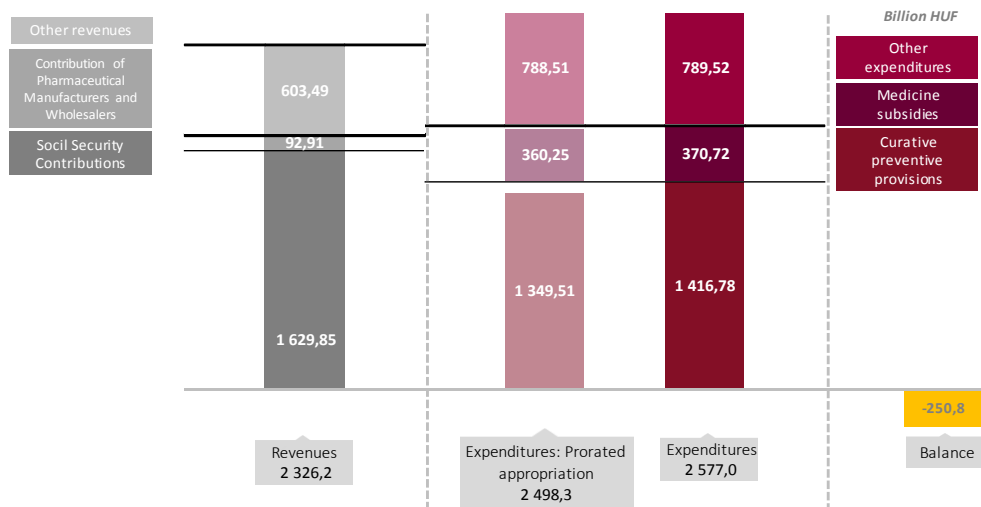


News, current issues

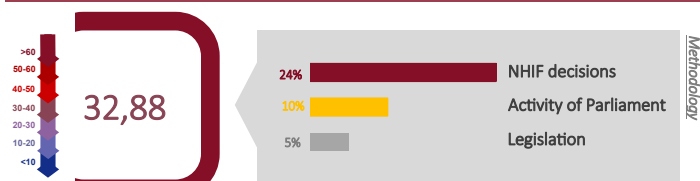
- News Healthcare system after the termination of gratuity >>
- News Effectiveness and safety is the key aspect in vaccinations >>
- News Pharmacies have been stormed: these medicines are in target >>

Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund, November 2020



Decision-making index, November 2020



Product offering

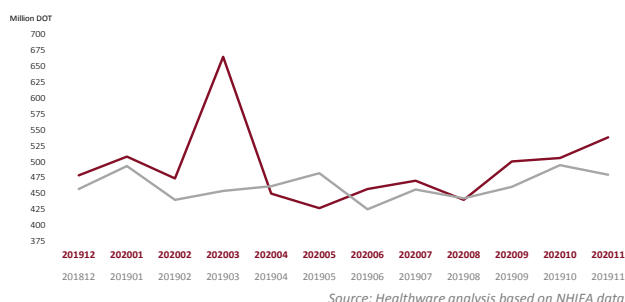
Market forecast

Healthware efficiently simulates market situations by developing and improving complex econometric models using economical-statistical estimators. Based on these models Healthware forecasts turnovers and can provide various scenario analyses.

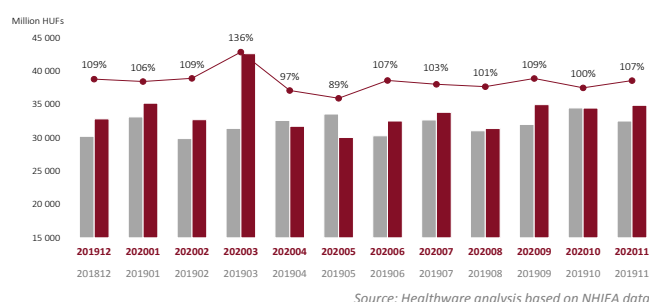
For further information, please visit our website or contact our colleagues: [link](#)

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

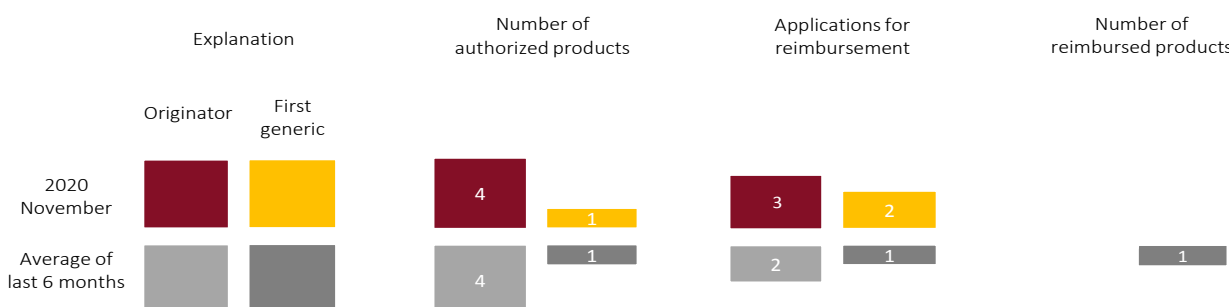
Pharmacy DOT turnover



Pharmacy reimbursement turnover

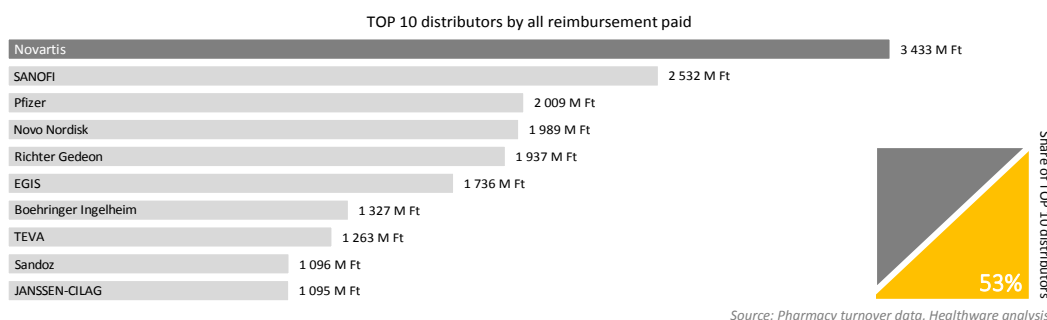
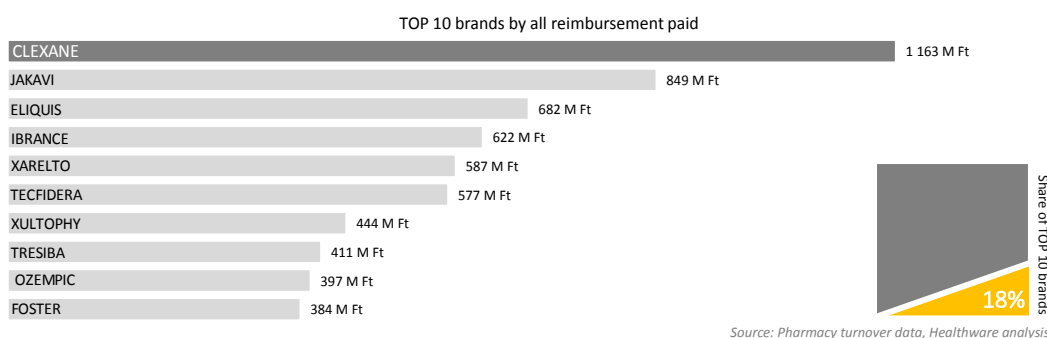
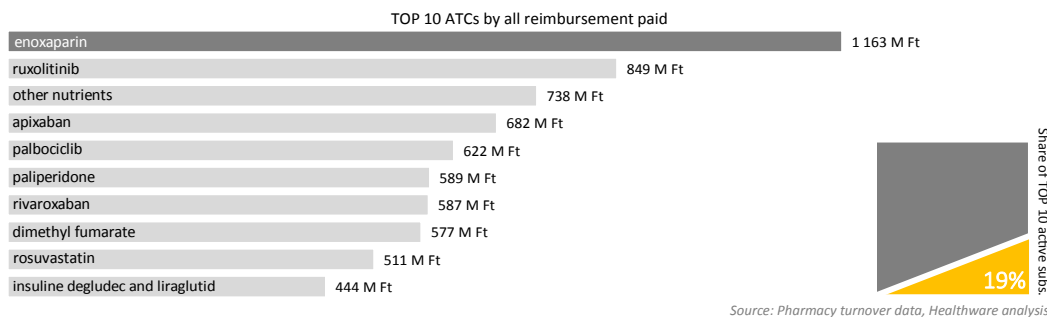


Changes to subsidized medicinal product categories, November 2020

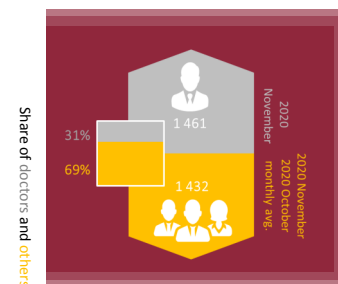


Market data

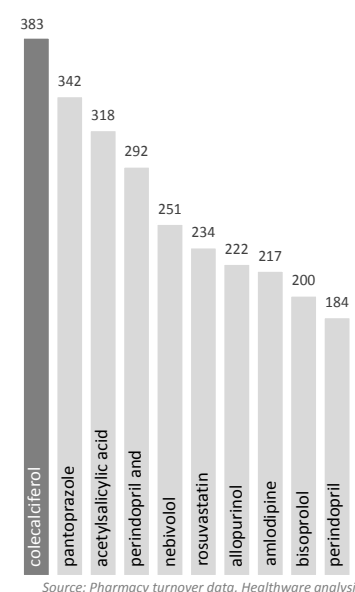
Toplists of reimbursement and number of patients, November 2020



Average number of medical sales reps



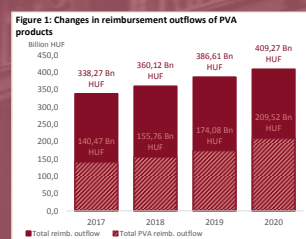
TOP 10 active substances by number of patients (thousand patients)



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

On January 6, 2021, NHIF¹ published the most recent list of existing price-volume agreements (PVA). The number of products with PVA contracts is showing a growing trend, thus playing an increasing role in the market of reimbursed pharmaceuticals. From 2020, this type of agreement can also be concluded for medicines with active substances already reimbursed in order to ensure the therapeutic value and health gain at a beneficial cost, taking into account health-economic considerations. In our case study, we review the content of these contracts, comparing with the previous list issued on 31 Dec 2019 (and other list from former years). Afterwards we refer to these documents as the 2020 and 2019 lists.

The lists contain only the main details of the contracts for each unit. In addition to the identification of the contractor and the product, the date in force (start and end dates of the contract), the type of fixed payment and the relevant indication (Eü point) are published in the PVA documents on an annual basis. Our analysis was only based on publicly available data sources.



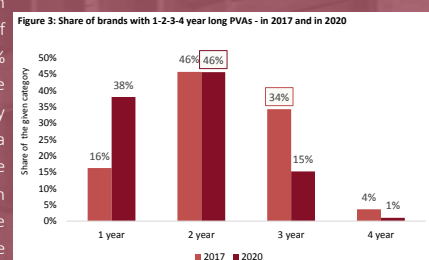
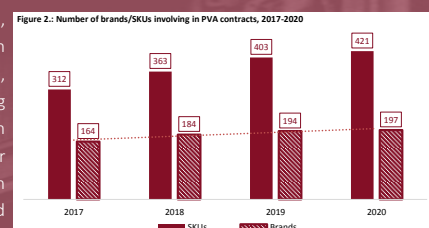
While in 2017, 41% of the total reimb. outflow was generated by PVA related products, until 2020 this share exceeded 50% (HUF 209.5 billion). This increase is also reflected in NPP² turnover. In 2019, the PVA products had 55% of the total NPP turnover (HUF 14.1 billion); but in 2020, the PVA contracts accounted for almost 63% (HUF 15.6 billion).

There is also a significant increase in the number of brands (Figure 2) involved in the agreements. Although the extent of growth is moderate in the 2020 list, but in comparison with 2018 it shows a slight 7% increase, and compared to 2017 we can see around 20% more brands (in terms of units a 16% and 34% growth can be observed).

¹ NEAK — National Health Insurance Fund
² Named-Patient Program

Healthware analysis based on NEAK data

Contrasting 2017 and 2020 (Figure 3), PVAs show a decreasing tendency in terms of average durations, presented in Figure 3. It is interesting to note that in 2017, the proportion of brands covered by a 1-year contract was significantly lower than in 2020, in the former it was around 16% and then rising to 38% by 2020. On the contrary, the inverse pattern can be observed in the proportion of brands with 3-year contracts at 34% first and then with 15% by 2020. The reason for shorter PVA periods may be that the decision maker has a favorable bargaining position in the renegotiation procedure, which can be enforced after the revision of the international price when setting the new price.



We divided the existing contracts into three groups to create a status classification. All units for which the main conditions (date, relevant Eü point, type of payment) have not changed (**un-changed condition**), remained in the same category. In all cases where we have seen an amendment to any of the above mentioned elements, it has been construed as a renewal (**renewed condition**) of the contract. Thus, this includes both contract extensions and changes in the type of payment or the relevant Eü point. **New** contracts encompass those

Continued on the next page...

Analysis of Price Volume Agreements (Part I) — Case study

Healthware analysis based on NEAK data

contracts that were not included in the previous list by categorization.³

Table 2: Comparison of the list 2019 and 2020

	Number of brands		Avg. period of contracts	
	2019	2020	2019	2020
Unchanged conditions	61	94	2,33	2,19
Renewed contract	104	86	1,77	1,33
New contract	41	25	1,80	1,45
All brands*	194	197	1,93	1,76

* The number of all brands is the distinct aggregation of the above listed category.
The different SKUs of a given brand may belong to different categories, hence appear in several categories.

Looking at the 2019 and 2020 lists - when the number of brands involved was around 200 -, we see that in 2020, completely new contracts were signed for fewer brands than in 2019. Contract renewals, on the other hand, were significant in both years; in the 2019 list, there were some changes in 104 cases compared to the previous list, while in the 2020 list for 86 brands.

A tendency to shorten contracts can be observed in Table 1 when examining the last two years. The average duration of contracts is 1.93 years in the 2019 list and 1.76 years in the most recent list. It is also shown in the data that the old PVAs, which remained unchanged, show an average of more than 2 years in both lists, while the new and re-negotiated contracts have been below 2 years. (in 2019 around 1.8 years; in 2020 between 1.3 and 1.45 years). Based on these findings, the trend is clearly to shorten the scope of contracts and to increase the frequency of renegotiations.

In Table 2, only those brands with an extended / re-concluded contract are considered for which a later date than the end of the validity is given in the certain list compared to the previous year. In the 2020 list, shorter contract lengths can be observed for most of the renewals than in the previous year. The average contract duration for the EÜ point amendment was reduced from 1.71 years (2019 list) to 1.20 years (2020 list). The average temporal scope also decreased if only the type of payment changed after the renegotiation, but to a lesser extent than for new indication points (2019: 1.93 years; 2020: 1.58 years). This may anticipate that if the contractually agreed indication point for a given brand has changed, the funder will strive for more predictable contract conditions, thus reducing any risks that may arise.

Table 3: Average contract duration of extended PVAs

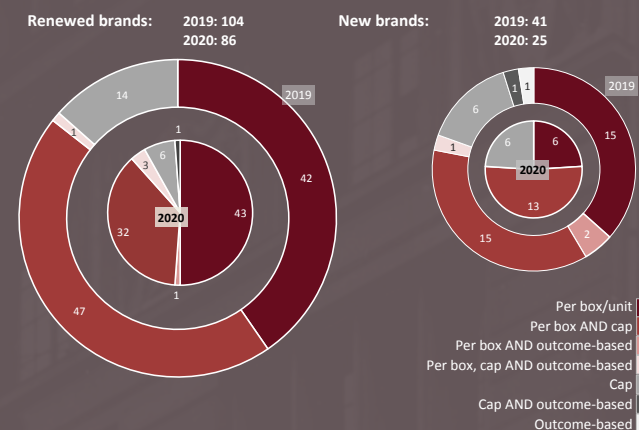
	Number of brands		Avg. period of contracts	
	2019	2020	2019	2020
Only extension	48	51	1,70	1,14
Extension and type change	10	15	1,82	1,63
Extension, type change and EÜ indication addition	5	2	1,86	1,98
Extension and EÜ indication addition	19	11	1,70	1,17
Total of extended contracts*	82	77	1,72	1,29

* The number of all brands is the distinct aggregation of the above listed categories.
The different SKUs of a given brand may belong to different categories, hence appear in several categories.

Analyzing the last four years, it could be said that instead of the initial contracts with per unit/box only or cap only condition, at present the number of per box AND cap contracts are the most commonly applied clawback methods. However, looking at the last two years, there is no such clear shift in the frequency of different payment types. Figure 4 examines new and renewed contracts each year by clawback type. Compared to 2019, the number of per unit AND cap contracts decreased in 2020, while the number of repayment per unit only increased somewhat. In 2020 fewer products (12 brands in total) had an outcome-based payment condition, although it is worth noting that its application is highly dependent on the therapeutic area; whether a performance-based contract can be defined. For newly concluded contracts on the 2020 list, in the vast majority per unit AND cap or only per unit or only cap forms of repayment methods have been applied.

³ Lines related to units that have been in force for years but appears for the first time have not been considered a new contract, except in cases where the contract has become effective since the previous publication.

Figure 4: PVA clawback methods in annual breakdown based on status**



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

The most common therapeutic subgroup among the PVAs is the drugs used in diabetes, involving more than 41 brands. This is followed by antineoplastic drugs and then drugs for obstructive airways diseases. Most renewals of anti-diabetic therapies happened due to extension, however, 2 new brands have also appeared in the category. For antineoplastic therapies, a change in the type of clawback can be seen for 5 brands, but there have been changes in the condition of some contracts due to new indication points.

Table 3: Number and types of PVAs by main therapeutic group

Therapeutic subgroup	Number of brands	Per box	Outcome-based	Cap
Drugs used in diabetes	41	41	0	19
Antineoplastic agents	28	28	1	6
Drugs for obstructive airway diseases	16	16	2	10
Immunosuppressants	13	13	3	4
Antivirals for systemic use	11	9	2	8

Concerning the types of contracts, it can also be said that repayment per box is the most commonly used method, however, in several cases, it can be supplemented by a cap contract. We have also seen examples of outcome-based reimbursement practices in the therapeutic areas of antineoplastic drugs, obstructive airways disease, or calcium homeostasis. In the 2020 list, the reimbursement method based on outcome has also appeared in the category of other hematological agents, which raises the question of the definition of endpoints and the evaluation criteria of patient registries based on real data.

Of the nearly 200 brand contracts, we can find a total of 59 that had a contract in force on 1 January 2021. This means that only 30% of the items listed provide the audience with up-to-date information. Assuming that the number of contracts will not change in magnitude - or will even increase - in the coming years, the renegotiation of PVAs and the conclusion of new contracts will require special attention and capacity from NHIF in the first half of this year.

All of these demonstrates that the number of PVAs is increasing for each product, so the definition of the contract conditions poses new challenges for not only the pharmaceutical stakeholders but the point of view of the decision-maker as well. After examining the contract lengths and their types, it seems that the current tendency of the conclusion of the contracts is to establish the defined conditions within an ever shorter, well-defined period, reducing the risks arising from any uncertainty factors (e.g. high price, lack of expected therapeutic effectiveness). In the next case study, we attempt to analyze how the funder develops his strategy, and examine in more detail based on the turnover the role of products with PVA in the pharmaceutical market.