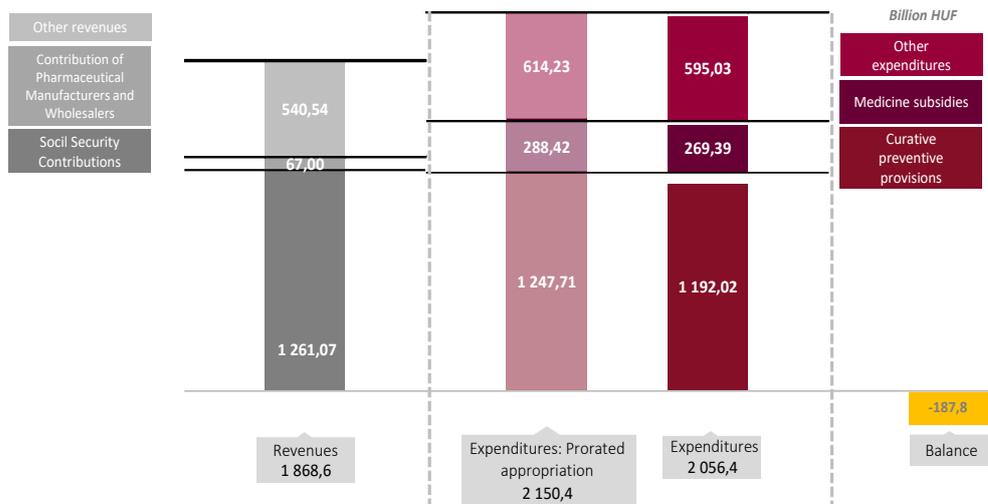


News, current issues

- News** There would not have been such a big pay rise in the Hungarian health sector if there is no pandemic >>
- News** Almost five thousand Hungarian cancer patients have disappeared due to the coronavirus pandemic >>
- News** Oliver Rozboril is the new President of the Innovative Pharmaceutical Association Manufacturers >>

Macro approach to financing healthcare and medicinal products

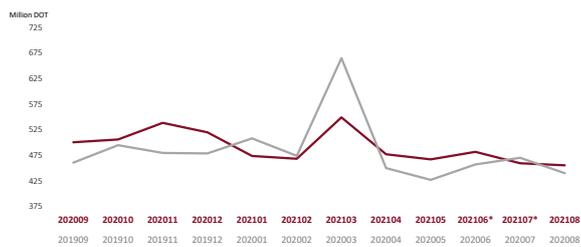
Balance of the Health Insurance Fund, August 2021



Source: Healthware analysis based on NHIFA data

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

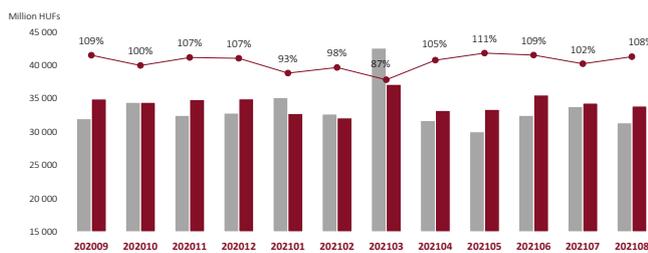
Pharmacy DOT turnover



*Note: Turnover data of SKU no. 210902238 is not displayed in DOT turnover figure (vitamin D3) - DOT 200,000 days -, this product first appeared in June 2021, as it significantly distorts the DOT turnover values as well as the overall market performance. The reimb. turnover of the SKU was taken into account.

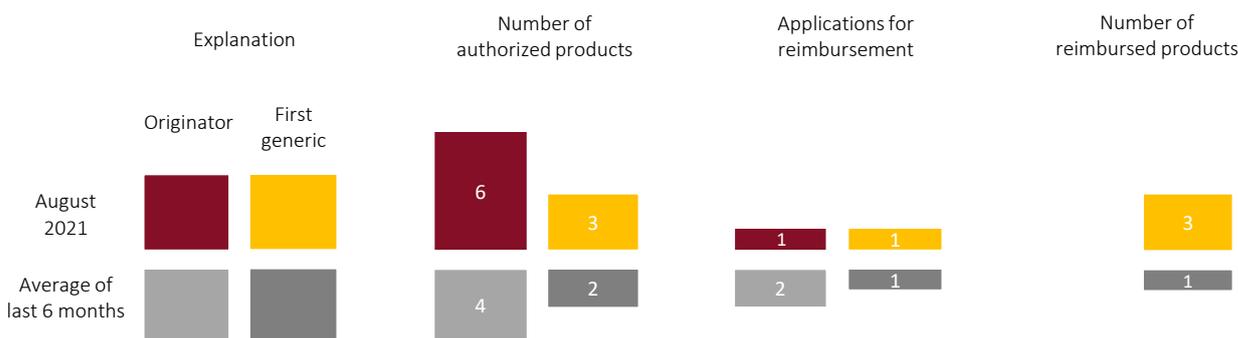
Source: Healthware analysis based on NHIFA data

Pharmacy reimbursement turnover



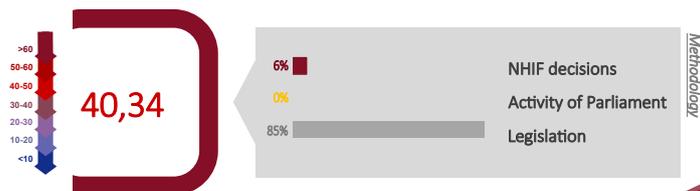
Source: Healthware analysis based on NHIFA data

Changes to subsidized medicinal product categories, August 2021



Source: Healthware analysis based on NHIFA data

Decision-making index, August 2021



Product offering

Budget impact simulation models

Illness/subgroup-specific budget impact analysis that reflect the actual uses, and simulation platforms built upon these analysis are becoming more important role in domestic acceptance mechanism.

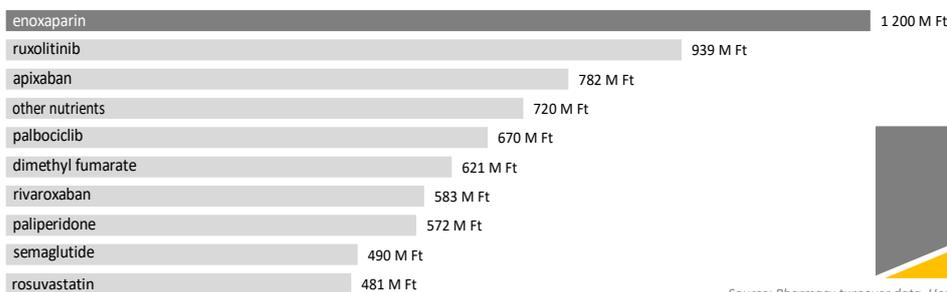
The simulation models built on National Health Insurance Fund data offer well understood and controllable dimension for the expected budget impact calculations for the decision maker.

More about the service: [link](#)

Market data

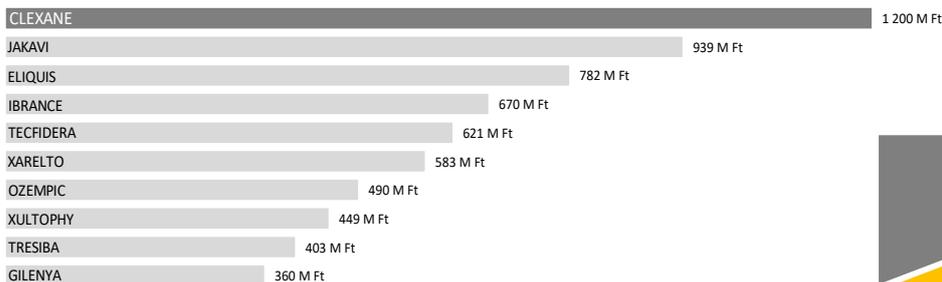
Toplists of reimbursement and number of patients, August 2021

TOP 10 ATCs by all reimbursement paid



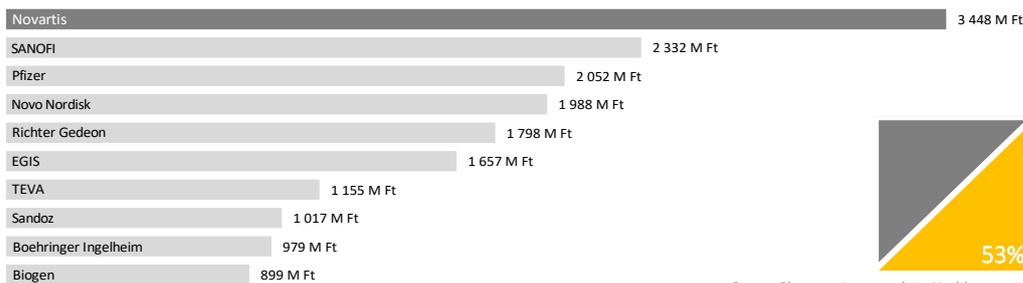
Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



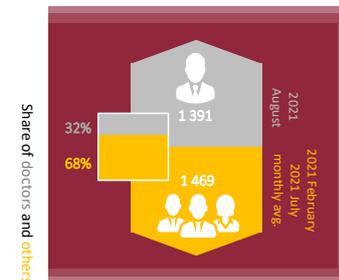
Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



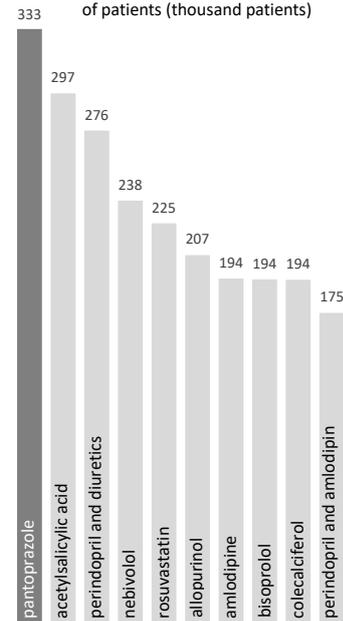
Source: Pharmacy turnover data, Healthware analysis

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

Extending outcome base financing — Case study

The aim of this current case study is to find out which therapeutic areas might be affected by the legislative amendment came into force on 29 June 2021, in which the mandatory outcome-based financing during the inclusion procedure was introduced. The Hungarian regulatory and infrastructural conditions have already been provided opportunities for outcome-based financing. Accordingly, this type of financing is included in the current risk-sharing techniques. We distinguish between three main types: box fee, volume cap and the outcome-based contracts; and the combination of these are also widely used.

Based on publicly available data, in December 2020 there were 199 brands concerned in any price-volume agreement, while only 5% of the brands had outcome-based agreement. It is important to note that based on market feedbacks, these contracts do not include the classic elements of outcome-based financing. This statement is also supported by the fact that most of the concerned products are nutritional products.

The amendment to the Act XCVIII of 2006 (Gyftv), published on 29 June 2021, may lead to a turning-point in terms of the price-volume agreements, since the legislator clearly outlines its long-term objective of which making outcomes-based financing part of daily practice in as many therapeutic areas as possible. Based on this legislation, the reimbursement inclusion can be approved only with outcome-based financing for all new active substance or for new indication, if in the first 3 years following the inclusion, the average yearly reimbursement outflow is likely to exceed the 0.3% of the original appropriation for the financing line of Drug reimbursement expenditure¹. This amount will be 999,42 million HUF in 2021, while in 2022 it will be 1031,41 million HUF.

The aim of our analysis was to find out how many therapeutic areas, brands will be affected by this legislative amendment.

Table 1: Substances meeting the criteria - pharmacy budget

Therapeutic area	ATC code	BRAND	Average yearly reimb. outflow (billion HUF)
Oncology	L01XE18	JAKAVI	2,98 billion HUF
Diabetes	A10AE56	XULTOPHY	2,37 billion HUF
Onkology	L01XE33	IBRANCE	6,28 billion HUF
Diabetes	A10BJ06	OZEMPIC	3,3 billion HUF
Onkology	L01BC59	LONSURF	1,53 billion HUF
Immunosuppressants	L04AA40	MAVENCLAD	1,22 billion HUF
Antithrombotic agents	B01AC21	TRESUVI	1,26 billion HUF

At first, we focused on the pharmacy budget, where we examined how many new active substances have been included to reimbursement since January 2016 that exceeded one billion HUF in the years following their inclusion. For the first two products data for 3 years were available from the date of inclusion; the annual average reimbursement outflow in the case of the first product was almost 3 billion HUF, while for the second product it was 2,3 billion. For Ibrance and Ozempic only 2-2 years of data were available, both exceeded the limit of 1 billion HUF. For the last three brands only 1 year of data is available since these are quite newly included products. However, based on this the new regulation, it would be mandatory to conclude outcome-based financing in these cases as well.

In case of reimbursement inclusion to the itemized accounting budget - containing high-value active substances -, outcome-based agreement is expected for almost all new active substances. To support this statement, we examined the actual expenditures of itemized substances included on 15 October 2018, detailed in the 2019 budget bill². For most of these active substances the public procurement started only in the second half of 2019 so the actual expenditure for 2019 does not include the whole year. Even with this restriction, most substances generated more than 300 million HUF outflow³.

Table 2: Actual itemized expenditures - substances included on 15/10/2018

Therapeutic area	ATC code	Act. substance	Total expenditure 2019
Oncology	L01XC13	pertuzumab	0,96 billion HUF
Oncology	L01XC32	atezolizumab	0,7 billion HUF
Oncology	L01XC24	daratumumab	0,68 billion HUF
Oncology	L01XE36	alektinib	0,45 billion HUF
Immunosuppressants	L04AA33	vedolizumab	0,39 billion HUF
Onkology	L01XX45	karfizomib	0,34 billion HUF
Immunosuppressants	L03AX16	szekukinumab	0,31 billion HUF
Onkology	L01XC14	trastuzumab em	0,26 billion HUF
Immunosuppressants	L04AC13	ixekizumab	0,2 billion HUF
Onkology	L01XE16	crizotinib	0,15 billion HUF
Immunosuppressants	L04AA29	tofacitinib	0,1 billion HUF
Immunosuppressants	L04AA37	baricitinib	0,09 billion HUF

Table 3: TOP ATCS groups - pharmacy budget

ATCS group - therapeutic area	Number of ATC7s	Reimb. outflow/ ATC7 (billion HUF)	Substances waiting for EMMI decision
L01XE - Oncology	4	10,57 billion HUF	5
B01AF - Antithrombotic agents	5	3,26 billion HUF	
A10AE - Diabetes	11	1,45 billion HUF	
L04AA - Immunosuppressants	8	1,89 billion HUF	3
B01AB - Antithrombotic agents	8	1,58 billion HUF	
N05AX - Psycholeptics	5	2,19 billion HUF	
R03AK - Obstructive airway diseases	9	1,1 billion HUF	1
A10AB - Diabetes	3	3,13 billion HUF	
A10BD - Diabetes	5	1,86 billion HUF	
C10AA - Lipid modifying agents	4	2,27 billion HUF	
V06D - Nutrition	25	0,34 billion HUF	
R03AL - Obstructive airway diseases	12	0,64 billion HUF	
N07XX - Other nervous system drugs	4	1,8 billion HUF	
N03AX - Antiepileptics	14	0,46 billion HUF	
A10BX - Diabetes	13	0,46 billion HUF	
C09BA - Agents acting on the renin-angiotensin system	4	1,28 billion HUF	
B01AC - Antithrombotic agents	6	0,83 billion HUF	1
L02AE - Endocrine therapy	5	0,98 billion HUF	
L01XX - Oncology	7	0,65 billion HUF	2
A16AX - Other alimentary tract and metabolism products	1	4,45 billion HUF	

Extending outcome base financing — Case study

Healthware analysis based on NEAK data

We examined whether there are any new active substances currently waiting for EMMI decision and may therefore be affected first-hand by the implementation of the legislation. We found five therapeutic areas like this, three of which have reimbursement per active substance currently above one billion HUF. All five groups include less than ten reimbursed active substances currently.

Currently, the new legislation only concerns the new active substances and indications. However, if the scheme is applied to a new active substance entering a therapeutic area, it is possible that the funder – in the light of the already defined endpoints, measurement, and monitoring methodology – will wish to enforce performance contracts in the same way to high-volume products already on the market, when renegotiating the price-volume agreements. The market of NOACs could be a good example for that, where we see three brands in the TOP list of brands, considerably above the one billion thresholds.

It is difficult to imagine that outcome-based agreement applied for a possible newly entering active substance would not be extended to incumbent active substances over time. From this point of view several therapeutic areas and products could be involved in medium-term consequences of the legislative amendment. Examining the products with the 15 largest reimbursement outflows in 2020 we find that without exception they are all over 1 billion HUF (the same applies for the TOP25 brands). If the circumstances (endpoints, methodology) are clarified due to a new entrant, the specified conditions can easily be applied to these permanently high-value products in the future.

Table 4: TOP 15 brands based on reimbursement outflow 2020 - pharmacy budget

Ranking	ATC code	Therapeutic area	Brand	Reimb. outflow, 2020 (billion HUF)
1	B01AB05	Antithrombotic agents	CLEXANE	11,49 bHUF
2	L01XE18	Oncology	JAKAVI	9,79 bHUF
3	L01XE33	Oncology	IBRANCE	7,51 bHUF
4	B01AF02	NOACs	ELIQUIS	7,32 bHUF
5	B01AF01	NOACs	XARELTO	6,78 bHUF
6	N07XX09	Other nervous system drugs	TECFIDERA	6,72 bHUF
7	A10AE56	Diabetes	XULTOPHY	4,94 bHUF
8	A10AE06	Diabetes	TRESIBA	4,69 bHUF
9	N05AX13	Psycholeptics	XEPLION	4,3 bHUF
10	R03AK08	Obstructive airway diseases	FOSTER	4,29 bHUF
11	L04AA27	Immunosuppressants	GILENYA	4,27 bHUF
12	A10BJ06	Diabetes	OZEMPIC	4,07 bHUF
13	A16AX01	Other alimentary tract and metabolism product	THIOGAMMA	3,76 bHUF
14	B01AE07	NOACs	PRADAXA	3,58 bHUF
15	L01XE08	Oncology	TASIGNA	3,42 bHUF

The legislation amendment in focus is also expected to change the direction of current price-volume agreements, with a move away from box-fee and cap agreements towards performance-based contracts. The question is how the National Health Insurance Fund (NEAK) - which is already struggling with human resource problems - will be able to cope the administrative burden of outcome-based financing and whether the planned change of direction is possible under the current conditions.

1: Act XCVIII of 2006 (Gyftv) - [link](#)

2: Budget Bill 2019 - [link](#)

3: The budget bill for 2020 does not include this information, so it is not possible to confirm the calculation on the basis of actual data for a full year.