HEALTHWARE

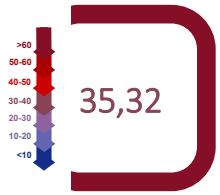
# Actualities of Hungarian pharmaceutical financing market

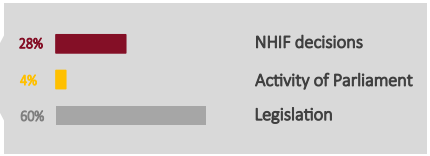
Newsletter
No. 11 Issue IX. 2021
Published: 01/12/2021

## News, current issues

- News: Not possible to ban door-to-door delivery of medicines according to the Association of Pharmaceutical Wholesalers »
- News: Instead of loopholes - Promotion rules in practice »
- News: Hungarians stormed pharmacies again »

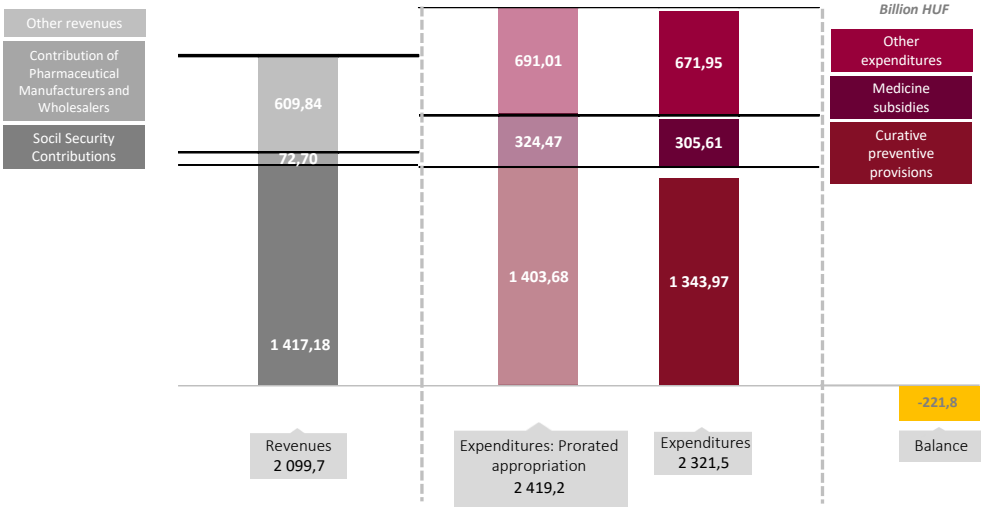
## Decision-making index, September 2021




## Macro approach to financing healthcare and medicinal products

### Balance of the Health Insurance Fund, September 2021




*Source: Healthware analysis based on NHIFA data*

## Product offering

**Public turnover data in our Medalyse service**

With our service Medalyse for our clients, public turnover data published by NHIFA is easily available and it is possible to follow them with time series analysis.

The turnover data is available in the end of the following month after the given month.

Healthware takes under to upload the data in the information system of Medalyse, if it is possible within 1 workday.

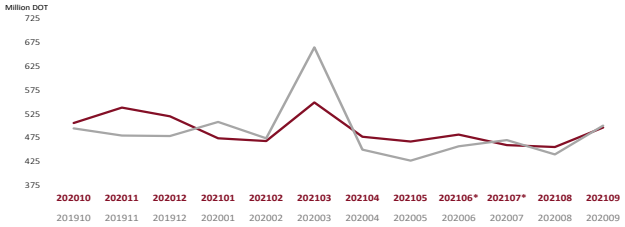
Therefore our clients are free to reach and analyze the turnover data of NHIF on the 20th day after the given month.

Detailed description about the data published by NHIFA: **link**

Details about Medalyse: **link**

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

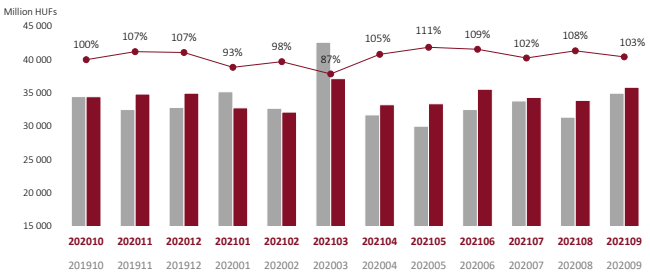
### Pharmacy DOT turnover




**Note: Turnover data of SKU no. 210900238 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.*

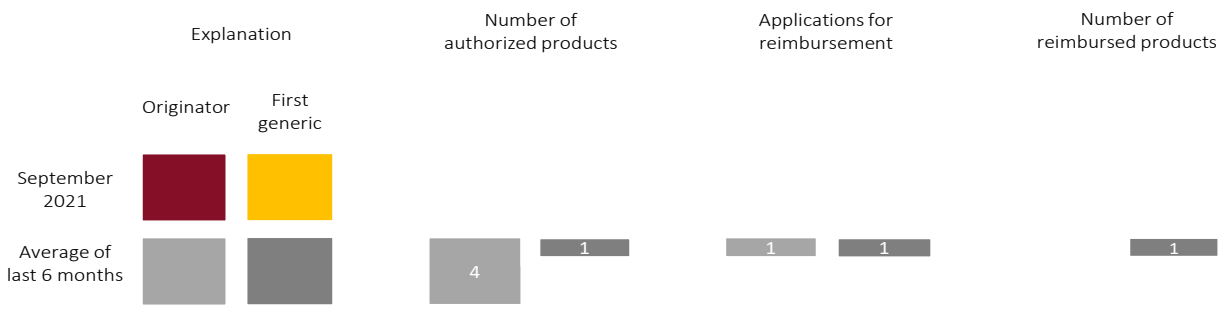
*Source: Healthware analysis based on NHIFA data*

### Pharmacy reimbursement turnover




*Source: Healthware analysis based on NHIFA data*

## Changes to subsidized medicinal product categories, September 2021




*Source: Healthware analysis based on NHIFA data*

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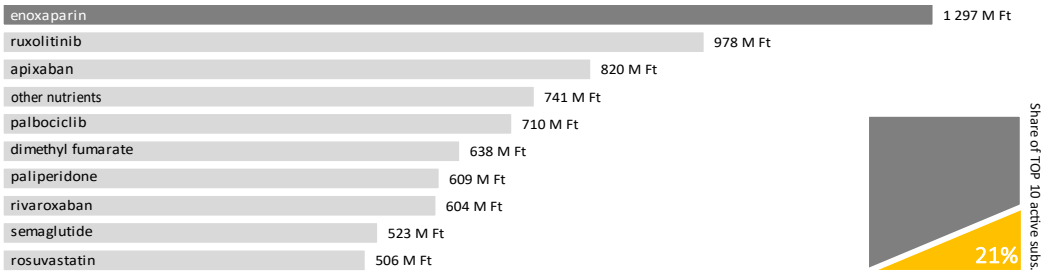
## Market data

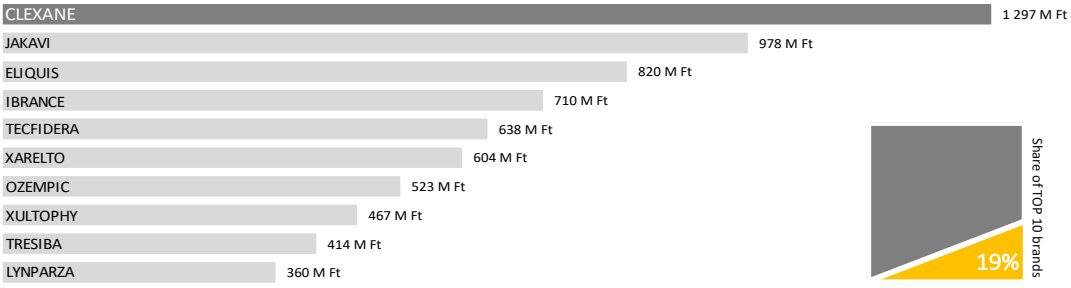
### Toplists of reimbursement and number of patients, September 2021

TOP 10 ATCs by all reimbursement paid



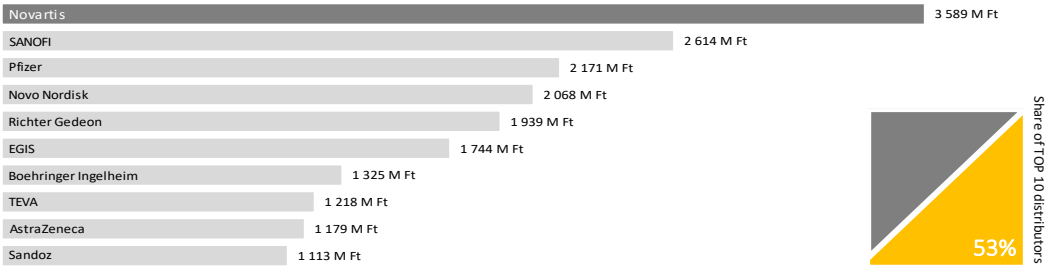

Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



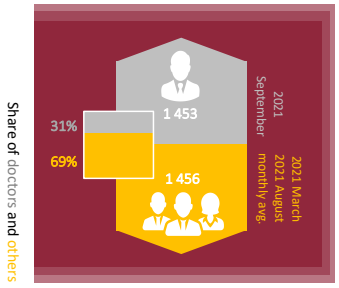

Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



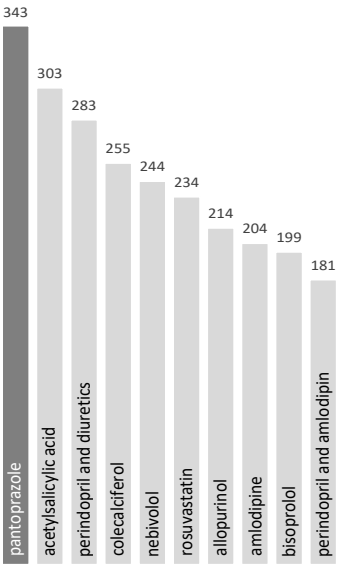

Source: Pharmacy turnover data, Healthware analysis

### 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 reimbursement submissions waiting for MoH decision — Case study

*Healthware analysis based on NEAK data*

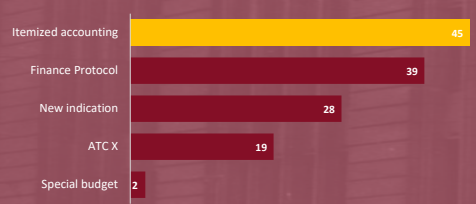
By the end of November 2021, 95 applications (52 brands) were pending in NEAK (National Health Insurance Fund), for which a change in legislation is required for the assessment, therefore NEAK cannot take a final decision on its authority. NEAK submitted these applications to the Ministry of Health (MoH) for a final decision in two phases, in September and October 2021.

*Based on Act XCVIII of 2006 [Gyftv.], in the case of applications requiring legislative amendments, NEAK sends its proposal to the Ministry of Human Resources (EMMI) at specified intervals in accordance with the decision of the TÉB. Transparent traceability of the procedures initiated in relation to the applications submitted is ensured from the moment of submission to the moment of referral to the Ministry. Thereafter, no public information on the rest of the process will be available until the final decision or the publication of the official communication.*

It is important to note that this is the first time in the last 5 years that NEAK has submitted a new package of medicines to the Ministry before the drugs in the previous submission have been published. The question may arise whether the new products will appear together with the applications submitted last year in the Hungarian Gazette or whether the two packages can go their separate ways, independently of each other.

In our case study, we looked at the 95 products proposed in the autumn of 2021 to the EMMI, from different perspectives - 48 of which concern the pharmacy budget, 45 the itemized accounting and 2 the special budget.

Figure 1: Number of submissions by reasons for legal amendment

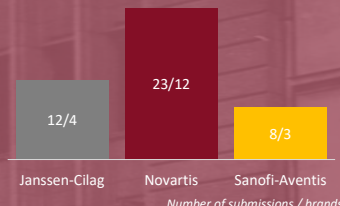



First, the reason for referral were examined for the submissions. Basically, there are 5 different reasons for reimbursement inclusion with a need for legal amendment – inclusion to the itemized reimbursement, change in the funding protocol, new health indication, inclusion in the special budget and the absence of ATC X in Annex 1 of Decree No 32/2004 (26/04/2004) of the ESzCsM on the category of the requested reimbursement. Figure 2 shows the distribution of these reasons among these 95 applications.

Where more than one reason was involved in an application, we classified the application under each category. Given that half of the applications target itemized accounting budget, it is not surprising that the most common reason for a change in legislation is the amendment to Decree 9/1993 NM.

Among the applicant companies Novartis, Janssen-Cilag and Sanofi-Aventis were the top three, with the most submissions. In terms of both the number of applications filed and the brands concerned, Novartis was the highest ranked.

Figure 2: TOP3 company




*Number of submissions / brands*

Applications were analyzed in terms of typical lead times, broken down into phases according to the individual decision points and stages. When interpreting the analyses, it is important to bear in mind that following the 2018 legislative change, the timeliness of tracking medication applications poses problems, as processes must be completed within 360 days.
For submissions that appear to extend beyond this, companies often take the initiative to close the process by terminating it and then resubmit them later without any changes, or with possible minimal changes. In our time-series analysis, if an application was closed with a termination order and the same application was resubmitted within a few months, it was considered as a resubmission. For these products the date of initiation was defined as the date of the first submission.

The average time between the submission and its proposal to the Ministry was 345 days, of

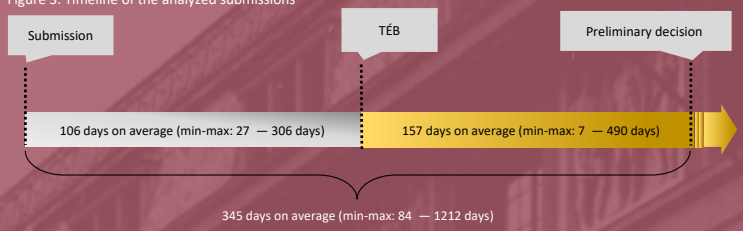
## Analysis of reimbursement submissions waiting for MoH decision — Case study

*Healthware analysis based on NEAK data*

which an average of 106 days were spent between the submission and the first TÉB meeting. This period also covers the possible completion of the application, the examination of international reference prices and the preparation of the evaluations of the competent advisory board and the OGYI TéF.

The average time interval between the last TÉB and the referral is 157 days. This period is the classical price negotiation period between NEAK and the manufacturing companies, when, according to the decision of the TÉB, the possible risk-sharing conditions have to be defined.[1]

Figure 3: Timeline of the analyzed submissions




Given that the currently not reimbursed products are funded on an individual basis as NPP, both the administrative burden and the outflow of pharmacy budget associated with these products are a serious problem.

[1] *In our timeline analysis, we split the procedure time till MoH proposal into two phases, which appears in Figure 3 as a continuous timeline. However, according to the methodology, the sum of the two plotted phases and calculated period does not necessarily equal the full timeline, since the first phase is calculated from the first TÉB meeting to the proposal to MoH, while the second phase is calculated from the last TÉB meeting to the proposal to MoH. This kind of discrepancy may appear more often in the case of re-submissions.*

In Table 1, we have collected the NPP turnover of the brands waiting to be included - in the last 12 months available alongside the published data. Products of active substances that are procured by NEAK through public procurement and for which a framework agreement has already been concluded for a previous indication will not appear in the table, since in this case the individual requests will be charged to the framework agreement.

Table 1 : MAT NPP turnover

| Brand | Reimbursement outflow - HUF (2020.11.01-2021.10.01) |
|---|---|
| AIMOVIG | 1 288 800 |
| AJOVY | 916 386 |
| BAVENCIO | 309 554 480 |
| BEOVU | 1 099 824 |
| CABOMETYX | 1 030 815 115 |
| CALQUENCE | 4 038 128 |
| DUPIXENT | 855 176 494 |
| DYSPORT | 13 967 764 |
| ELMIRON | 81 435 433 |
| ENTRESTO | 1 338 223 |
| ERLEADA | 25 595 946 |
| FAMPYRA | 1 279 333 |
| IMNOVID | 860 100 300 |
| LEQVIO | 10 406 409 |
| LIBTAYO | 949 878 994 |
| LYNPARZA | 3 343 933 788 |
| OCREVUS | 1 741 338 919 |
| OFEV | 224 858 175 |
| OLUMIANT | 3 335 000 |
| POLIVY | 925 796 019 |
| REVOLADE | 618 633 434 |
| TYSABRI | 7 328 582 |
| XARELTO | 578 333 |
| ZEJULA | 21 983 100 |
| **Total** | **11 034 676 978** |

The 11 billion HUF MAT reimbursement outflow of the products detailed in Table 1 gives appr. 40% of the estimated annual NPP turnover for 2021. In a previous case study, we analyzed in detail that the NPP appropriation would cover the financing of treatments inherently covered by this title, but the dramatic increase of NPP volumes is due to the turnover of products waiting for reimbursement inclusion, which should not be financed under this budget.

The funding of these products should be found from other sources. Their funding under the NPP scheme is not sustainable in the long term, it represents a heavy administrative burden for the Payer, and highlights the protracted and socially overburdening impact of the inclusion procedures - highlighting that, in this present procedure, there are many therapies waiting for inclusion for which there is currently no funded therapeutic regime.