HEALTHWARE

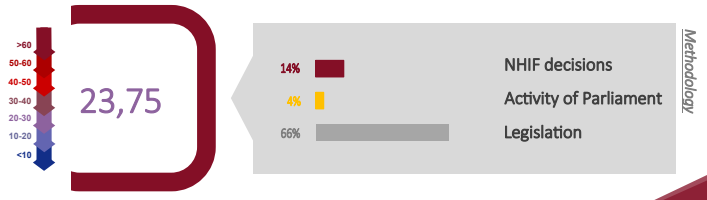
# Actualities of Hungarian pharmaceutical financing market

Newsletter
No. 6 Issue IX. 2021
Published: 07/09/2021

## News, current issues

- News: Average funding scheme shall cease »
- News: Half of HCPs are considering quitting »
- News: New molecule has been investigated in Debrecen University, it may be used in cardiac therapy »

## Decision-making index, April 2021



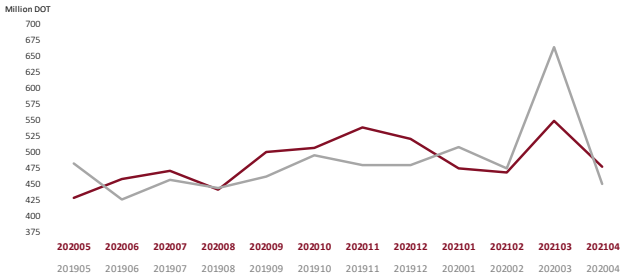

## Macro approach to financing healthcare and medicinal products

## Balance of the Health Insurance Fund, April 2021


*Source: Healthware analysis based on NHIFA data*

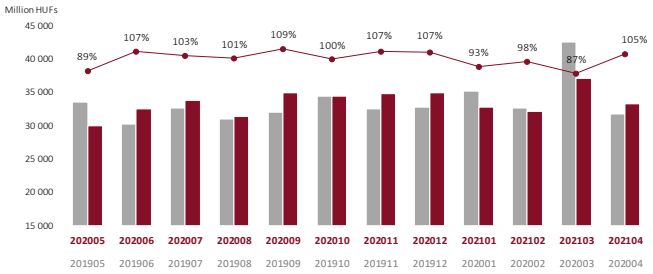
## Dynamics of the sales/circulation of prescription-only-medicine

### Pharmacy DOT turnover



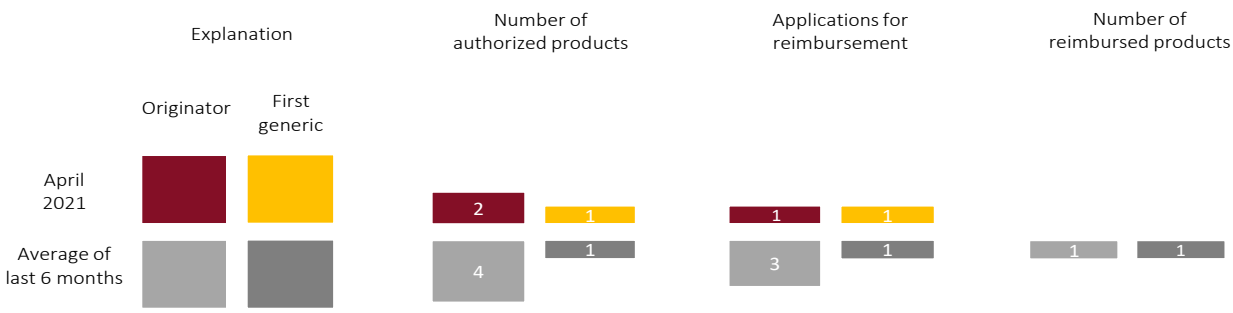

*Source: Healthware analysis based on NHIFA data*

### Pharmacy reimbursement turnover




*Source: Healthware analysis based on NHIFA data*

## Changes to subsidized medicinal product categories, April 2021




*Source: Healthware analysis based on NHIFA data*

## Product offering

**Indicator system development**

Quality indicators are needed for evaluate a therapy at macro level. The individual micro-level knowledge enables to seek/elaborate parameters which allow to build up an indicator system.

With the comprehensive knowledge acquired along our micro-level analysis products we can ensure elaboration of systems, which show the success of certain medical technologies in transparent way, with objective parameters.

More about the service: **link**

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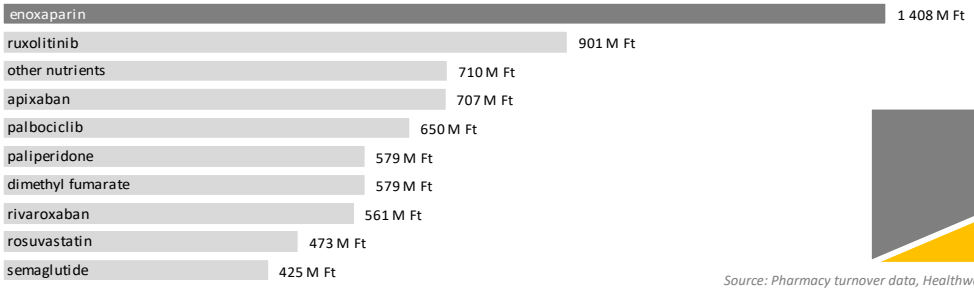
## Market data

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

TOP 10 ATCs by all reimbursement paid

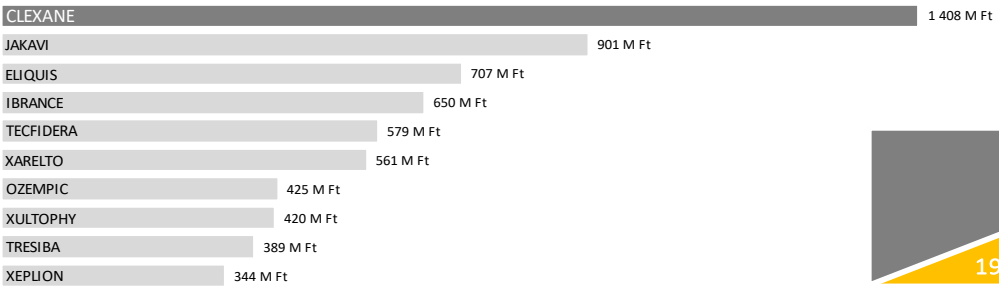






*Source: Pharmacy turnover data, Healthware analysis*

TOP 10 brands by all reimbursement paid

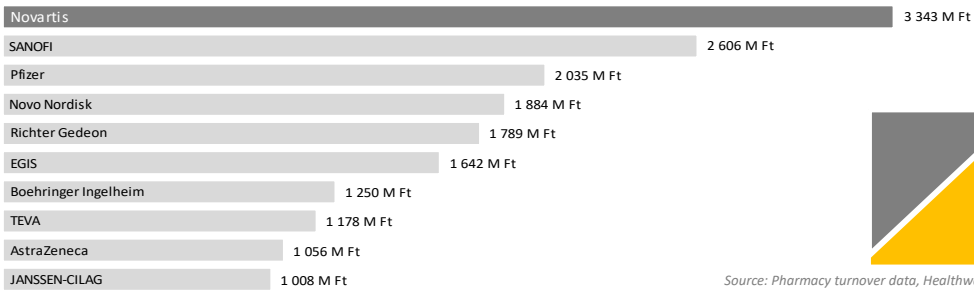






*Source: Pharmacy turnover data, Healthware analysis*

TOP 10 distributors by all reimbursement paid

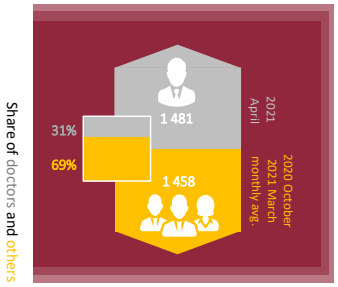






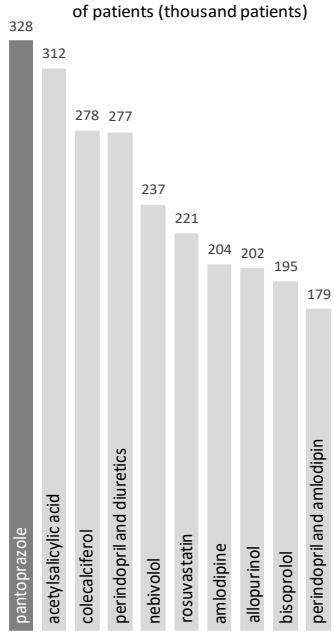
*Source: Pharmacy turnover data, Healthware analysis*

### 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 submissions decided on the NEAK's own power — Case study

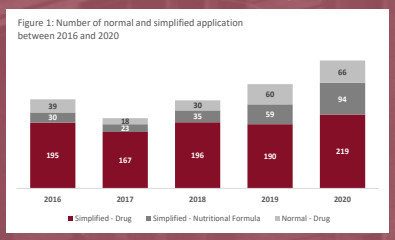
*Healthware analysis based on NEAK data*

In the case study of May 2021, covered those applications for reimbursement were covered for which the final decision is not the competence of the NEAK. The composition and lead time of these submissions were reviewed. In the current case study, we examine the other side of the coin, those applications for drug reimbursement that NEAK may decide on its own power, without legal amendment. Our analysis was based on the list published by the NEAK, in which the procedures initiated for the application in the period between 01.01.2016 and 31.12.2020 were examined.

The concerned applications may be divided into two segments, applications judged under the simplified procedure and the applications judged under the normal procedure. The two different procedures are subject to separate rules, both as regards the documents to be submitted and the rules on adjudication. Hence, these categories are examined separately in the analysis.

Figure 1 shows the number of applications launched between 2016 and 2020 in the group of both normal and simplified applications. The dossiers assessed in the latter type of procedure were divided into two further categories, applications for medicinal products and applications for nutritional formulas. With regard to the fact that nutritional formula applications may only be evaluated under a simplified procedure, we did not carry out this additional division into subcategories in the case of the normal applications.

Figure 1: Number of normal and simplified application between 2016 and 2020




In the last 5 years, the majority of applications awaiting a NEAK decision are not surprisingly consist of simplified procedures; applications for new formulations, strengths, packaging, generics, etc. of already reimbursed active substances.

On an annual basis, 30-60 such dossiers were submitted, for which a normal procedure is required, but the assessment has not been required a change in legislation (eg. instance, a new drug, a form of administration, a price increase).

[1]*NEAK—National Health Insurance Fund of Hungary*

| Simplified procedures | Normal procedures |
|---|---|
| In case of an active substance have already been approved for reimbursement | |
| new formulation | new route of administration, new formulation |
| new strength | new indication |
| new formulation and same route of administration | new active substance |
| new generics, brand name | new combination (if one of the active substance has not yet been approved for reimbursment) |
| new packaging | price increase |
| new nutritional formula | change in reimbursement category |
| application for preferential status | cases of a combination specified in specific other legislation |
| new biosimiler | for a new medicinal product with an active substance have already been reimbursed, with the exception of the provisions of Section 4 of Government Decree 452/2017 (XII. 27.) |
| combination containing an active substance has already been approved for reimbursement | A product with a significant therapeutic benefit reimbursement at a higher price and determination of the reimbursement |

Analyzing both groups, significant growth can be observable from 2017 onwards; in the case of simplified procedures, 65% more applications were initiated in 2020 than in 2017 (we can see a threefold increase in the number of applications for nutritional formulas and there is also a 30% growth in the case of medicines), while for normal procedures an average of 30 applications were submitted between 2016 and 2018, then between 2019 and 2020, 60 and 66 applications were submitted, respectively.

Our experience has shown that the vast majority of applications in the normal procedure include such medicinal products that, for example, did not fit into the criteria of the simplified procedure due to a lack of equivalence or a deviation from the necessary price rule.

Regarding the requested reimbursement categories, it can be clearly visible that the indication-based 100%, indication-based 50%, 70%, 90%, and normative reimbursement categories were the most frequent in all the three examined groups. In addition, the number of itemized accounting applications for simplified procedures has also been outstanding. It is important to note that the submissions of the itemized accounting funding category for innovative preparations containing a new active substance require legislative amendment without exception, since all of the active substances are listed and set out in the relevant legislation into the pre-determined indication category.

| Reimbursement category | Simplified | | Normal (Drug) | Total |
|---|---|---|---|---|
| | Drug | Nutritional formula | | |
| Indication-based 100% | 256 | 77 | 95 | 428 |
| indication-based 50%, 70%, 90% | 322 | 119 | 67 | 508 |
| Normative | 320 | 127 | 84 | 531 |
| Hospital | 4 | 0 | 3 | 7 |
| Special budget | 29 | 0 | 14 | 43 |
| Itemized accounting | 133 | 0 | 25 | 158 |

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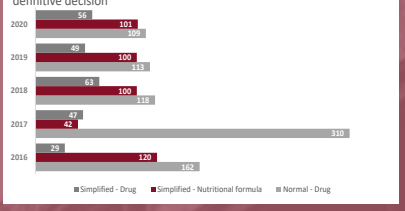
For this reason, all the products classified in the itemized accounting category but assessed without legislative amendment according to a simplified or normal procedure can be concerned as the inclusion of a generic molecule.

### PROCEDURAL TIMES

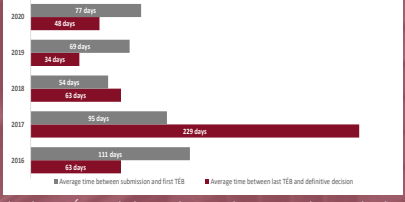
As in our previous case study, our intention was to raise the issues of the length of the procedural times.

Figure 2: Average number of days between submission and definitive decision




We first examined the average number of days between the submission of the application and the final decision. Until 31.12.2017, in the case of the simplified procedure, NEAK had 60 days to evaluate the applications, however, from 01.01.2018, the funder shall/may take a decision on each application within 90 days, in accordance with the normal procedure. Nevertheless, we can see average processing times longer than 90 days for both nutritional formulas and normal procedures. An explanation of this longer duration of proceeding is that the manufacturer may request a maximum breakdown period of 180 days according to the Act CL of 2016 on General Public Administration Procedures.

Figure 3: Average number of days elapsed at the stages in the process of reimbursement admission




Subsequently, we carried out a more detailed analysis of the normal procedures, where the average number of days from the submission of the application to the first TÉB meeting were evaluated and then between the last TÉB[2] meeting until the final decision was made. In the latter case, higher-than-expected averages were obtained. In 2017, there was an average of 229 days between the last TÉB and the inclusion decision, when only the detailed conditions need to be concluded to close the applications.

### DECISIONS

The following table shows the distribution of applications with positive decision, rejection or termination during the observed period. Based on that, it can be stated that about 85% of the initiated applications are accepted according to the decision of the NEAK, among which the medicinal products under the simplified procedure with positive decisions are outstanding with a 92% frequency. Rejection decisions were made almost exclusively in the case of nutritional formulas, while applications with a suspension, albeit with a lower percentage, but appear in all three categories.

| Year | Positive decision | | | Rejection | | | Suspension | | |
|---|---|---|---|---|---|---|---|---|---|
| | Simplified | | Normal (Drug) | Simplified | | Normal (Drug) | Simplified | | Normal (Drug) |
| | Drug | Nutritional formula | | Drug | Nutritional formula | | Drug | Nutritional formula | |
| 2016 | 92% | 77% | 72% | - | 23% | 8% | 8% | - | 21% |
| 2017 | 93% | 91% | 78% | - | 9% | - | 7% | - | 22% |
| 2018 | 86% | 80% | 93% | 1% | 3% | - | 13% | 17% | 7% |
| 2019 | 95% | 76% | 87% | - | 3% | 2% | 5% | 20% | 12% |
| 2020 | 92% | 73% | 67% | - | 9% | - | 5% | 11% | 21% |

### PRICE INCREASES

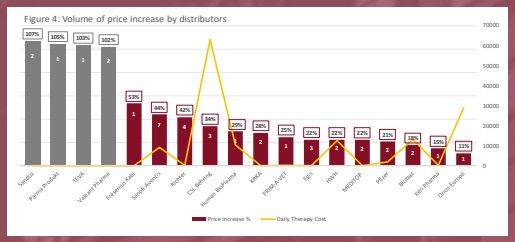
| Year | Price increases with positive decison |
|---|---|
| 2016 | 6 |
| 2017 | 4 |
| 2018 | 8 |
| 2019 | 22 |
| 2020 | 17 |

In accordance with the current applicable legislation, the price increase of a reimbursed medicinal product can only be initiated upon request, in a normal procedure. In the following, we have analyzed in more detail the requests for price increases where NEAK made a positive decision (the decision outcome can be deduced from the public data).

[2] *TÉB—Technológia-Értékelő Bizottság, HTA Committee*

Any price change where the producer price assigned to a certain SKU was increased, between the beginning and the end of the observed period, was considered a price increase. Based on this methodology, the figure below shows the rate of the average percentage of price increases accepted by the funder over the last 5 years in a distributor breakdown.

Figure 4: Volume of price increase by distributors

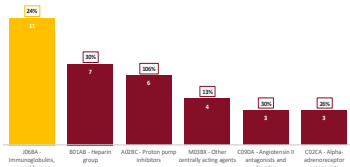



| Applicant | 12 month DOT turnover before the price increase |
|---|---|
| Sandoz | 98 402 821 |
| Parma Produkt | 917 471 |
| TEVA | 148 |
| Valeant Pharma | 173 401 |
| Fresenius Kabi | 86 176 989 |
| Sanofi-Aventis | 41 821 494 |
| Richter | 19 402 685 |
| CSL Behring | - |
| Human BioPlazma | - |
| KRKA | 27 144 750 |
| PRIM-A-VET | 65 307 |
| Egis | 47 957 918 |
| HWH | - |
| MEDITOP | 14 386 275 |
| Pfizer | 7 522 000 |
| Biotest | - |
| Kéri Pharma | 302 978 |
| Onco-Europe | - |

The TOP price increases are due to the presence of a generalized active substance that had a shortage in supply on the reimbursed drug market for a certain period of time and was subsequently re-introduced as a "new active substance" in the reimbursed formulations, at a higher price. Examining pharmacy products, the majority of price increases were requested by generic drug manufacturers, however, most of these types of applications can be linked to a single innovative manufacturer.

In the fifth figure, we examined the rate of average price increases based on ATC5. The price increases affecting most brands were in the group of human immunoglobulins, which are funded through public procurement. On average, the rate of price increases is between 20 and 30% for each group, the only prominent group is the PPIs, which have been included in reimbursement as a result of the special market circumstances described earlier.

Figure 5: Volume of price increase by ATC5 groups




### CONCLUSION

It can be concluded that on an annual basis, the ever-increasing number of applications represents a serious administrative burden for the funder. Due to the greatest extent of growth in the submissions for nutritional formulas, it may be desirable introducing new aspects into the assessment process.

In recent years, more and more manufacturers are requesting price increases for their products, but it should be pointed out that based on past practice, we have found that in the majority of the cases the extent of public price increase requested by the manufacturer is claimed back by the NEAK in the form of box fees. Thus, for the funder, the price increase does not imply an actual increase in reimbursement outflows, but the position of the product in terms of international reference pricing is strengthened. It is clearly visible that a significant part of the concerned products is at a low level of therapeutic costs, hence it is assumed that the price margin of the products is no longer sufficient to cover the profit loss of the forint / euro exchange rate. In addition, there is a marked intention to increase the price of medicines made from human blood products, which is explained by the special nature of the active substance, but it is unknown that what extent NEAK is willing to tolerate these market expectations and how sufficient it will be to sustain a secure domestic supply.

A further question may be put as to how the new international reference pricing rules that have recently entered into force will affect the newly arriving price increase applications.