

## News, current issues

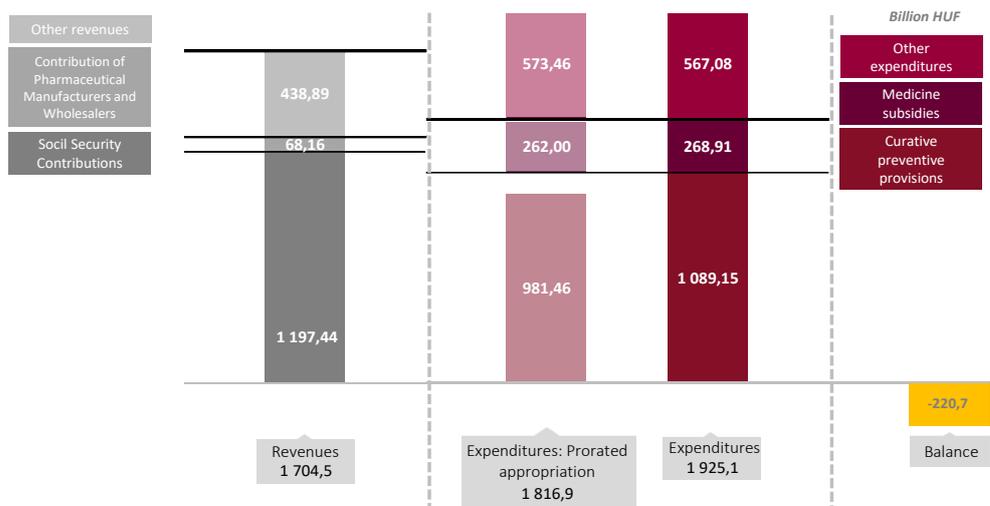
**News** Nearly a third of professionals leave health care because of the new law >>

**News** Customers have disappeared from pharmacies in Budapest - here is the explanation >>

**News** Within weeks, the controversial health law could be overwritten >>

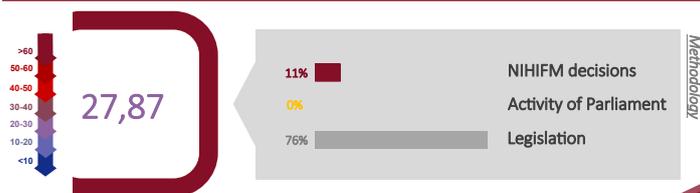
## Macro approach to financing healthcare and medicinal products

### Balance of the Health Insurance Fund, August 2020



Source: Healthware analysis based on NHIFA data

## Decision-making index, August 2020



Product offering

### Indicator system development

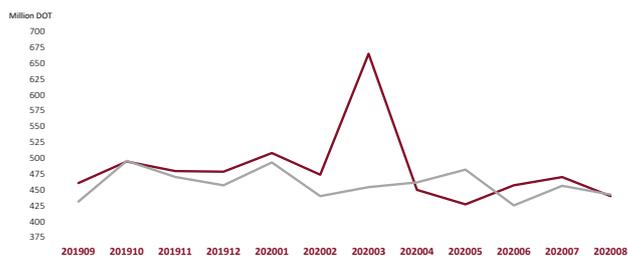
Quality indicators are needed to evaluate a therapy at macro level. The individual micro-level knowledge enables to seek/elaborate parameters which allow to build up an indicator system.

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](#)

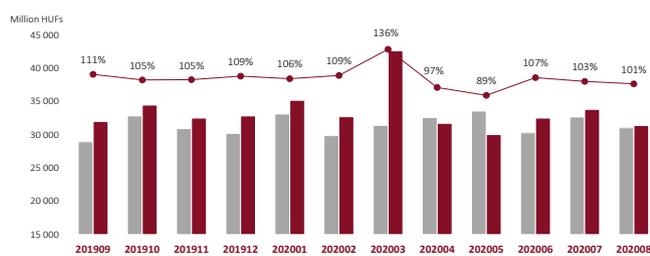
## Dynamics of the sales/circulation of prescription-only-medicine

### Pharmacy DOT turnover



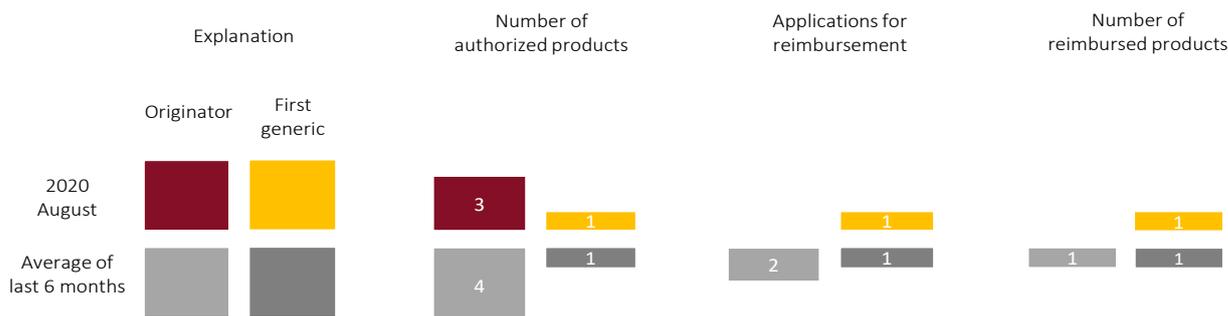
Source: Healthware analysis based on NHIFA data

### Pharmacy reimbursement turnover



Source: Healthware analysis based on NHIFA data

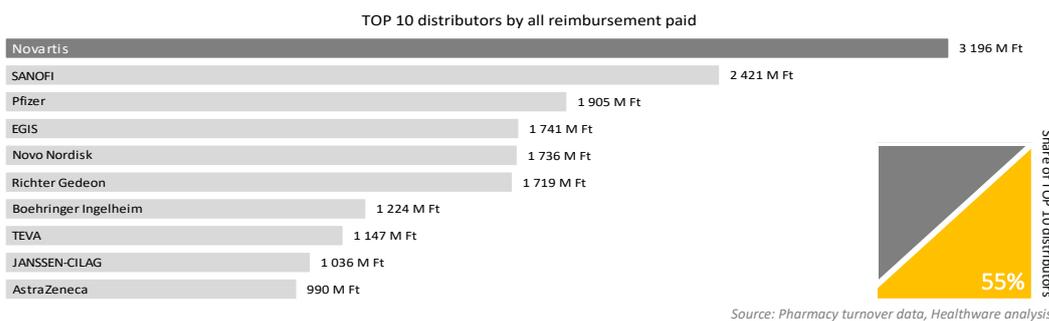
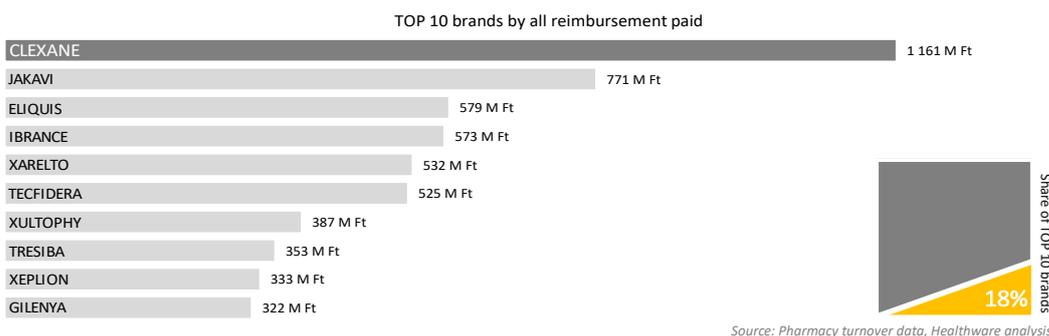
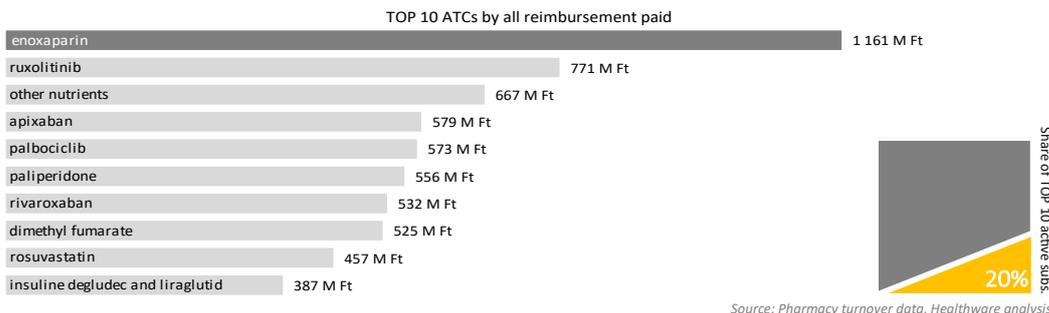
## Changes to subsidized medicinal product categories, August 2020



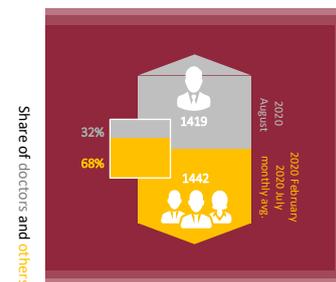
Source: Healthware analysis based on NHIFA data

## Market data

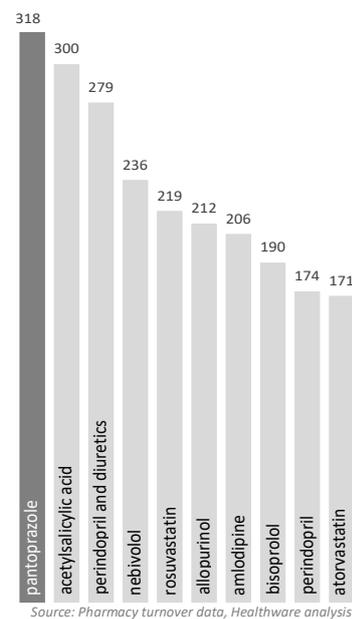
### Toplists of reimbursement and number of patients, August 2020



### Average number of medical sales reps



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



## Reimbursement inclusion of health technologies — Case study

In recent years, we have presented a number of newsletters on drug reimbursement inclusions. The list of weekly updated applications published by the NHIF<sup>1</sup> has been analyzed in detail, the pharmaceutical industry will pay a particular attention to any information on medicines submitted to MoH<sup>2</sup> for inclusion. COVID pandemic not only has direct therapeutic effects, but also reveals on a less focused area. The availability and technical parameters of ventilators, PCR tests, rapid tests, other medical devices and in vitro diagnostic tools (it is worth mentioning the sensitivity and specificity of laboratory tests) became part of the public discourse.

Taking the current increased interest, we aim to present the financing environment for health technologies excluding medicines - and medical aids - and to highlight the issues characterizing this area which have been swept under the rug. Respectively, we would like to draw attention to the anomalies that unduly affect the inclusion of these health technologies.

In the first part of our multi-part case study, we go through the inclusion of health technologies used in curative-preventive procedures, first examining the legal background, then presenting the practical anomalies that fundamentally make it difficult to place these technologies to market. We identified five problematic areas in the procedure, of which we include three in this case study, the remaining two will be presented next month.

"New health technologies can be included in the reimbursement system in a transparent and traceable way, following a fully-fledged health technology assessment." - www.neak.gov.hu

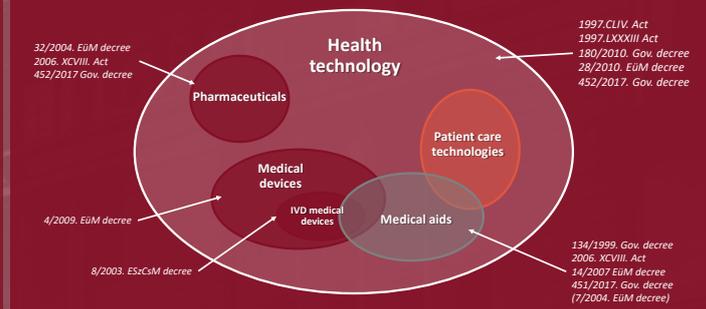
The reimbursement for medicines and medical aids, as well as their inclusion, operates in accordance with a separate legal act and procedure. NHIF has developed a separate procedure for health technologies applied in curative-preventive therapies as of July 1, 2010, but the past 10 years have revealed to a few shortcomings.

#### DEFINING THE SCOPE

The definition of the above mentioned technologies is concerned too general - covering a wide range of medical devices -, as well as activities that may be related to healthcare), however, the documentation

<sup>1</sup>National Health Insurance Fund (officially: NEAK)  
<sup>2</sup>MoH: Ministry of Health; officially: EMMI—Ministry of Human Capacity

## Classification of health technologies - Hungary



of this type of submission contains relatively few technologies. Thereby, it is also difficult to precisely determine based on public information in which cases the above mentioned procedures have to /or recommended to be initiated. Relying on our personal experience, the classification of technologies or the identification of financing type is not always clear to the payer.

Several medical devices are included in reimbursed as medical aids - bandages, hearing aids -, along with the related procedures, while others may be subsidized and used in health care processes within the framework hospital procurement or a national tendering. However, there are medical devices or medical procedures, in which case the payer eventually expects the initiation of the relevant / above-mentioned procedure, presumably in all cases where the certain medical technology cannot be financed under another procedure.

It is important to see that these technologies often belong to smaller distributors who have neither the routine nor the necessary apparatus to get through bureaucratic labyrinth. Thus, a new innovative technology often fails in the very first phase, simply because the distributor is not able to indicate an adequate financing method for him.

## Reimbursement inclusion of health technologies — Case study

### MCDA

The process is similar to that for drug reimbursement, except that the application of multiple-criteria decision analysis (MCDA) appears as a legal criterion in decision-making and that a decision with a possible positive decision at the end of the procedure does not imply automatic inclusion, only a preliminary a resolution (preliminary ruling for inclusion) stating that NHIF had assessed the particular technology and supported its reimbursement inclusion. However, MoH has retained the power to make the final decision, for which the legislation provides for a period of three years (!).

During the MCDA, each technology is evaluated on the basis of 20 criteria. From the final, maximum of 100 points, the final score/index is obtained according to the relevance of each aspect, which, if it exceeds 60 points, the evaluation of potential inclusion is considered as positive.

Peer-reviewed multi-criteria*	Maximum score
<b>I. Health priorities</b>	<b>20 points</b>
I.1. Public health programs	6 points
I.2. Policy priorities	7 points
I.3. Aggregate health gain	7 points
<b>II. Disease severity</b>	<b>15 points</b>
II.1. Life-threatening acute disease	13–15 points
II.2. Life-threatening chronic disease	10–12 points
II.3. Non-life-threatening acute disease	8–9 points
II.4. Non-life-threatening acute chronic disease	6–7 points
<b>III. Equality</b>	<b>15 points</b>
III.1. Affected patient population size	8 points
III.2. Availability, access	7 points
<b>IV. Cost-effectiveness, quality of life</b>	<b>30 points</b>
IV.1. ICER value	15 points
IV.2. Health gain per patient	15 points
<b>V. Aggregate budgetary impact</b>	<b>10 points</b>
<b>VI. Domestic and international professional judgment</b>	<b>10 points</b>
VI.1. Opinion of the professional administrations	3 points
VI.2. International application	3 points
VI.3. Classification of evidence related to the procedure	4 points
<b>Total</b>	<b>100 points</b>

\*28/2010. IV. 12. JEuM decree

The application Multiple-criteria decision analysis (MCDA) in the procedure is fundamentally desirable, as it could help to include factors such as equity, justice and innovation in decision-making, which may be far more important for medical devices than for medicines, despite the fact that the aspects set out in the regulation are mainly related to health economic analysis.

It raises essential concerns that, although the value of the maximum weight that can be assigned to each item set by law, the details of scoring are not sufficiently elaborated or are only not available transparently, which results the possibility of subjective scoring. In addition, priorities appear in the list (Health, Public Health and Policy Priorities) whose development is also unknown, and their assessment is highly uncertain.

For instance, the aspect of equality is emerging, but how to quantify it raises more questions - on what

basis can a technology be evaluated from 1 to 10, from the point of view of equal opportunities? (eg. Budget impact maximum of 10 points; What is 1 point - and what is 5 ?; Equal opportunities 15 points, what is 1 point, what is 10 or what is 15 points?)

### HEALTH ECONOMIC ANALYSIS

It is also worth emphasizing that health economics analysis and its results are given the greatest weight in the criteria analysis, while in the case of other health technologies other than medicines (hereinafter other technologies) the recommendations of the Professional Healthcare Guideline on the methodology of Health technology Assessment are difficult to understand, the interpretation of the results is far more complex than could be scored as a yes-no result. 30 out of 100 points can be obtained for proving cost-effectiveness.

However, the minimum requirement to be completed in the data sheet is only the “Health gain per patient” and “ICER value” (not analysis!).

Based on the presented first three aspects, it can be stated that the process is built on uncertainty – it is difficult to determine the exact content of the category. In addition, both the evaluation and the required methodology for submission need some level of modification and clarification to make the process transparent and efficient.

In our next case study, we will continue to explore the shortcomings of the current procedure, examining it in terms of transparency and administrative issues. As a conclusion to our analysis, we will summarize our suggestions for change in these essential topics.

The recommendations of Professional Healthcare Guideline on the methodology of Health technology Assessment for health technologies are difficult to apply:

- ◆ What level of clinical evidence can be expected for other technologies (eg. medical devices)? Randomized clinical trials?
- ◆ What costs should be considered for other technologies?
  - ◆ Procurement cost?
  - ◆ Operating cost?
- ◆ What are the options if quality of life data are not available for such technology or quality of life not even interpretable?
- ◆ How to perform the analysis if the technology does not have a comparator?