HEALTHWARE

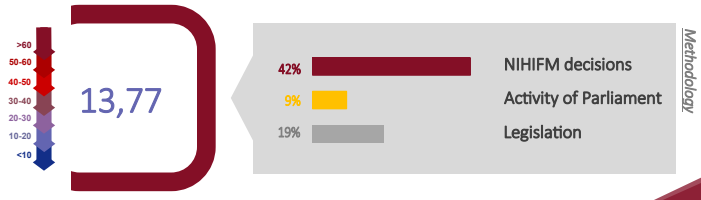
Actualities of Hungarian pharmaceutical financing market

Newsletter
No. 11, Issue VIII. 2020
Published: 19/11/2020

News, current issues

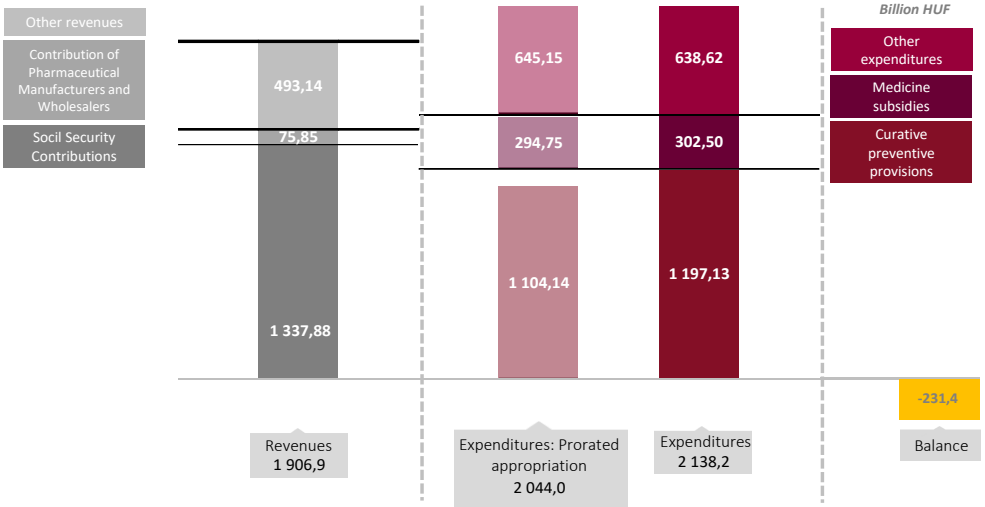
- News: The purpose of clinical trials is not to vaccinate half of the country - Interview with Csilla Pozsgay, a pharmaceutical expert »
- News: Hungarian Medical Association's Resolution on the new legal relationship for healthcare workers »
- News: Regulation of the medicine supply also rewritten by the government »

Decision-making index, September 2020



Macro approach to financing healthcare and medicinal products

Balance of the Health Insurance Fund, September 2020



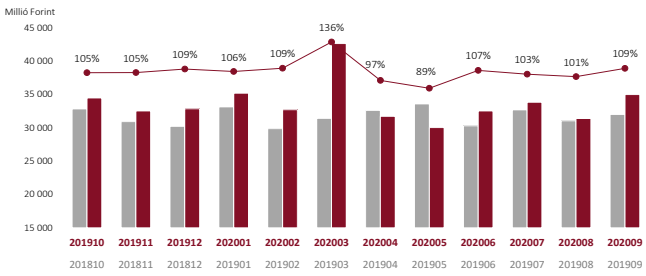
Source: Healthware analysis based on NHIFA data

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, September 2020

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**

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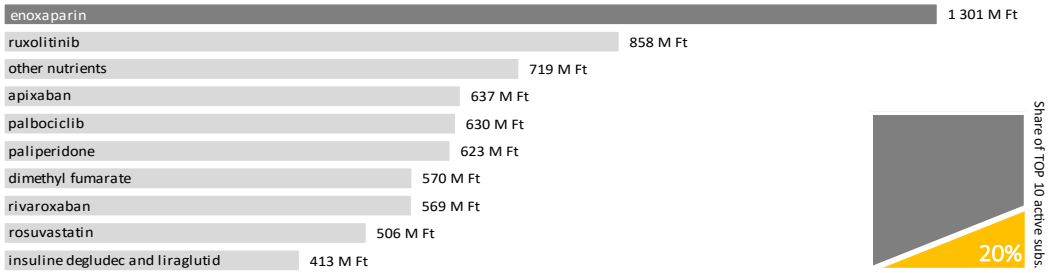
Market data

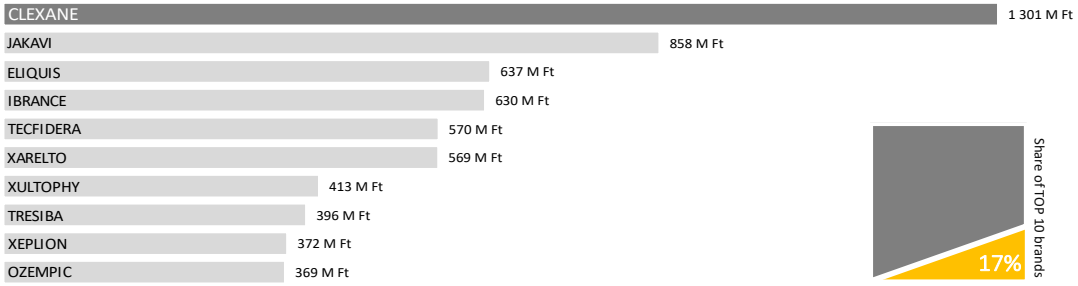
Toplists of reimbursement and number of patients, September 2020

TOP 10 ATCs by all reimbursement paid



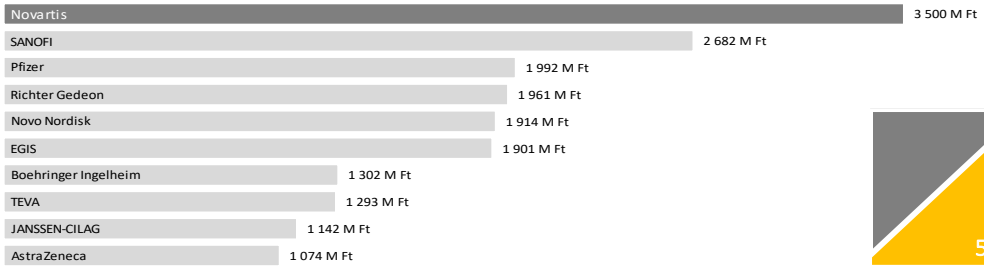
Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



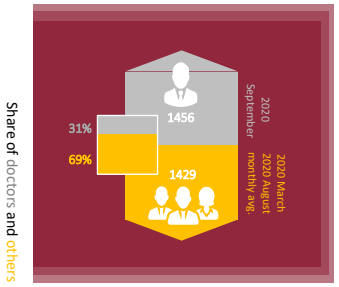
Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



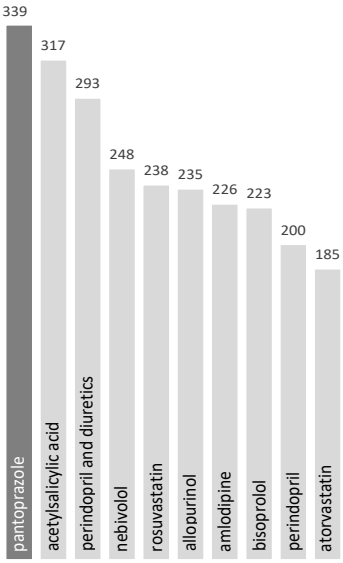
Source: Pharmacy turnover data, Healthware analysis

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

Reimbursement inclusion of health technologies — Case study (Part II)

In the first part of our multi-part case study, we examined the inclusion criteria of health technologies used in curative-preventive care. We have identified functional anomalies that fundamentally make it difficult for these technologies to enter the market. We drew attention to the uncertainty inherent in the definition of the product scope concerned, the problems with the methodology used in the submissions required for inclusion, and the shortcomings of the evaluation system. In the present study, as a continuation of the topic, we review the area of transparency and ongoing administrative challenges, and then formulate proposals for the transformation of the system.

TRANSPARENCY

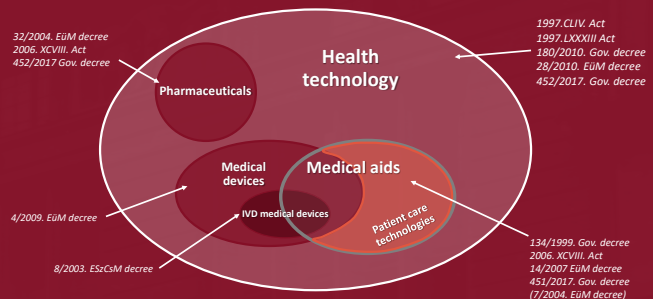
The decree does not provide guidance on transparency, traceability of the procedure, and while the rules of the preliminary inclusion procedure are sets out in detail, it as well as any information on the details of ministerial decision-making lasting up to 3 years. Transparency and traceability are regulated by the Act on Health Care[1], according to which - in the same manner as in the case of medicines - NHIF publishes information on the initiation of proceedings and the decision on the NHIF website.

Regarding the ministerial decision-making, the legislation only lays downs a time limit, so the actual process is completely unknown from public sources. The 'Payment Code Refinement Committee' is also involved in the process, but the basic information there is also lack of publicly available information of this Committee (decision-making mechanisms, criteria, composition of the committee) with regards to operation. Based on the concerns mentioned earlier, it can be stated, this stage of the procedure, which can be extended for a maximum of 3 years, takes place without any substantive information, where the final decision is made in a completely undefined way by unknown decision-makers.

It is only a parenthetical remark that a three-year delay is also very painful for a patented drug, but for a technology where the life-cycle is much shorter and technological innovations can appear much sooner, it can even be fatal.

[1] *Act CLIV of 1997 on Health Care*

Classification of health technologies - Hungary



According to the "Register of Technology Inclusion Procedures" available on the NHIF website:

Since 2010, 47 applications have been launched, the list includes the names of the Applicants, the subject of the Application and the date of initiation of the procedure. After October 2017, the notices initiating the procedure, containing the basic data of the procedure, have not been posted on the website, and for the last two years only the ongoing procedures are available. There is limited information on the preliminary ruling for inclusion and no information on the Ministry's final decision on the website.

The number of innovative medicines and the procedures for their acceptance is over a magnitude of 100 on an annual basis.Are there no more innovative technologies in Hungary, or would the procedure above not be aimed the reimbursement of innovative health technologies?

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ADMINISTRATIVE ISSUES

During the procedure, consultations are mostly limited to filling in the gaps. The data content of the application for inclusion in health technologies legislation refers to non-existent legal points, the data sheet and the annexes requested to be attached need to be revised due to inconsistencies between the content of the data sheets and parts of the professional criteria used in the final assessment.

Updating the datasheets would reduce the number of orders for supplementing documents, which could accelerate the process of application judgement. Unfortunately, these bureaucratic demands often conflict with inconsistent formal and substantive requirements, which the applicant cannot resolve with the best of intentions, so that the application can fail without a meaningful decision.
It would be appropriate to take over the administrative changes already applied to medicinal products, (such as the electronic submission instead of paper-based submissions).

CONCLUSION

Overall, the inclusion of health technologies other than medicines -and medical aids-, its legal background, raises a number of questions that may justify why we can only see information on so many reimbursement procedures.

An applicant who submits a reimbursement application for a new healthcare technology at the end, in addition to the legal difficulties can expect a number of bureaucratic obstacles, which is followed by up to 3 years of uncertainty after the preliminary ruling of the reimbursement inclusion procedure, and then patients may have the chance to access the publicly financed health technologies.

It would be desirable:

- At legislative level: the clarification of the uncertainties surrounding the subject of procedure, updating the application and its data content.

The deadlines declared in the legislation currently in force have not been feasible in practice since the entry into force of the General Administrative Procedure Act on 01.01.2018,

- In the case of initiated proceedings, the implementation of a greater degree of transparency (even of the manner shown in the applications for reimbursement for) by both NHIF and the Ministry processes,

- Clarification of the MCDA principles and would be more beneficial to apply / not apply these principles uniformly together with pharmaceutical technologies,

- If, in the case of health economic analyzes, the payer would recognize the differences between pharmaceuticals and other health technologies,

Increasing transparency is facilitated by the publication of procedural acts within the own competence of NHIF, similar to the inclusion of medicines:

- Requested indication
- Designated reimbursement category
- Date of HTA Committee meeting
- Publicly available Technology Assessment Department - HTA Summary
- Authority / NHIF decision
- The legal foundation on which the decision is based
- Date of submission to the Ministry

- A significant reduction in the maximum decision-making time period of the Ministry,

- Understanding in a broader perspective the work of the Payment Code Refinement Committee,

- More flexible and less bureaucratic design of processes.

In our case study, we attempted to highlight the interpretation and evaluation difficulties of the health technologies' inclusion, as well as expose other shortcomings of the procedure. We hope that aspects and proposals listed above may provide an appropriate basis for the more racional and transparent decision-making and that the issues discussed will be clarified.