HEALTHWARE

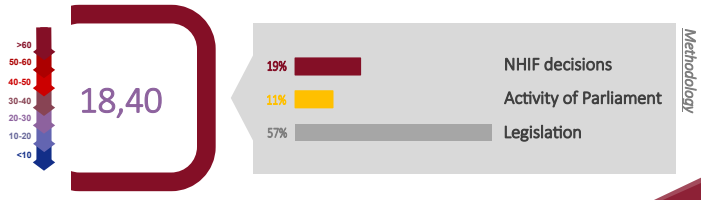
Actualities of Hungarian pharmaceutical financing market

Newsletter
No. 8 Issue IX. 2021
Published: 09/16/2021

News, current issues

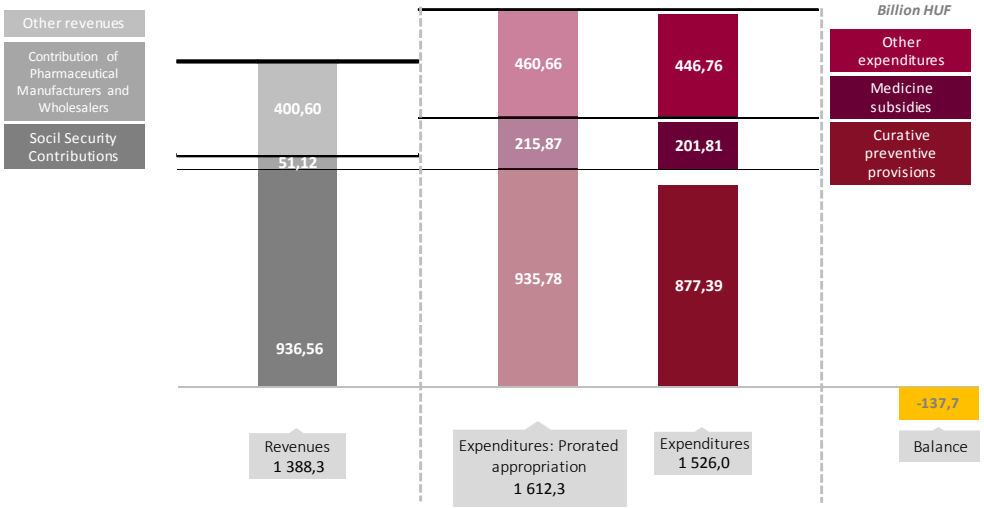
- News — Sales of prescription-only medicines have soared »
- News — Performance-based funding has returned »
- News — Survey was conducted on health awareness in Hungary »

Decision-making index, June 2021



Macro approach to financing healthcare and medicinal products

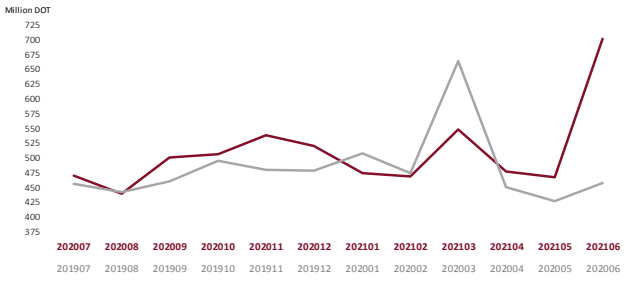
Balance of the Health Insurance Fund, June 2021



Source: Healthware analysis based on NHIFA data

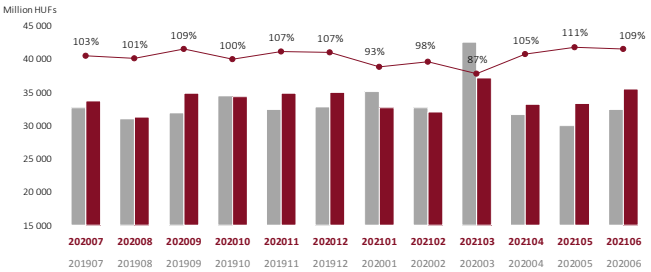
Dynamics of the sales/circulation of prescription-only-medicine

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, June 2021

Source: Healthware analysis based on NHIFA data

Product offering

FX-process/Reference pricing

Following the changes eventuated in the course of formation of FX-groups:

- Presentation of changes in group- and product level
- Modelling of forming of FX-groups:
  - Cancel and create groups,
  - Combine and dissociate groups,
  - Cancellation of products,
  - Translocation of products,
  - Change of price, reimbursement and DOT-values of products
- Analysis related to FX-process

According to the demand of Client we make decision preparatory and modelling analysis about fix groups related to the portfolio.

Further information about the service: **link**

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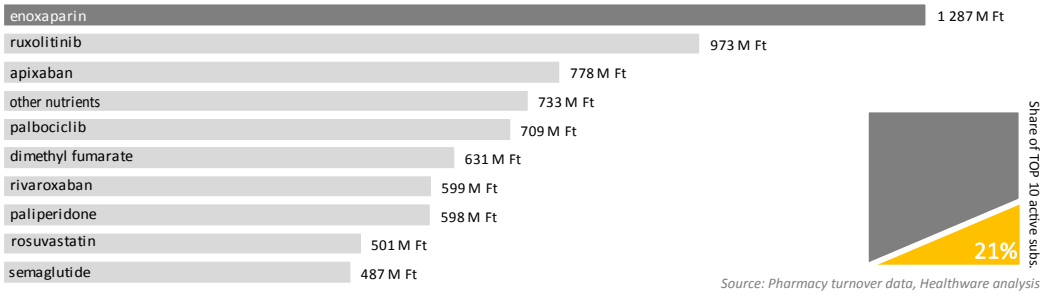
Market data

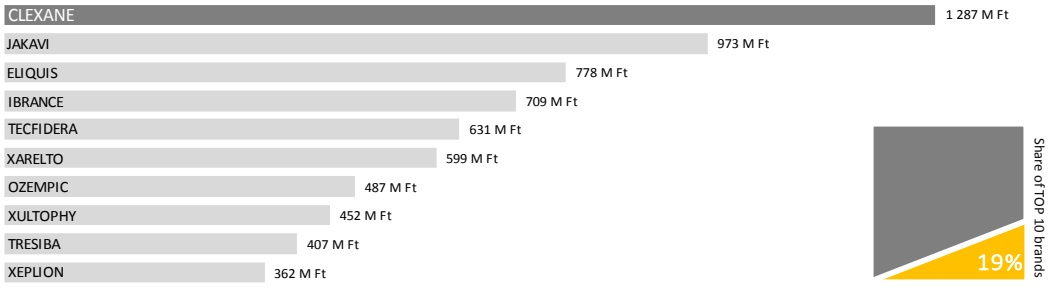
Toplists of reimbursement and number of patients, June 2021

TOP 10 ATCs by all reimbursement paid



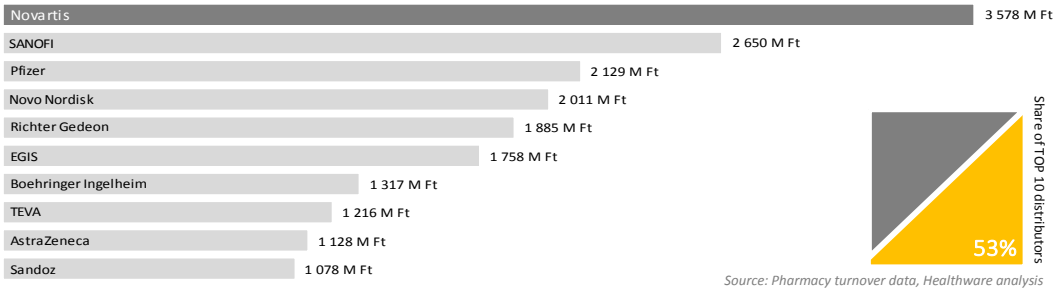
Source: Pharmacy turnover data, Healthware analysis

TOP 10 brands by all reimbursement paid



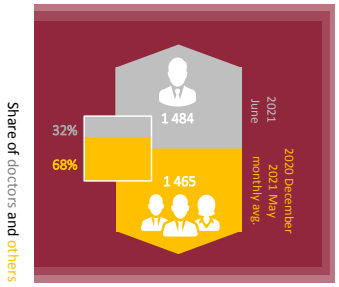
Source: Pharmacy turnover data, Healthware analysis

TOP 10 distributors by all reimbursement paid



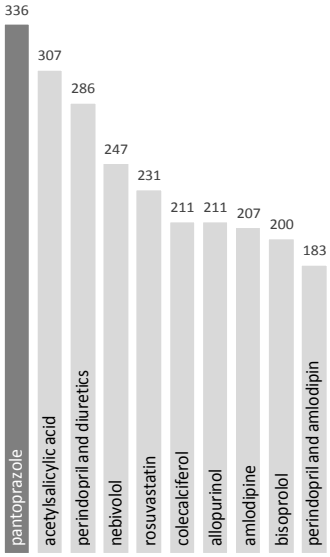
Source: Pharmacy turnover data, Healthware analysis

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

Preferential status — Case study

Healthware analysis based on NEAK data

In our current case study, a form of reimbursement, the preferential status is presented, introduced in the Act XCVIII of 2006[1] in 2014 (Gyftv.), emphasizing its benefits, describing the methods of implementation, and determining the poorly defined areas of the category. This special type of reimbursement shall only be requested by the distributor for a period of 5 years – at the time of the start of the admission procedure –, in cases when the therapeutic benefits of the medicinal product are unique, the shortage may result in health impairment and the same active substance is not available on the market in the same indication and route of administration.

Acquisition of preferential status provides numerous benefits to the distributor, such as avoiding external reference pricing as a part of the reimbursement procedure and the 20% tax calculated from prescription-based data; not having to pay the administrative service fee; in addition, the medicine may become available in the social welfare reimbursement category. This framework is also effective from the funder's perspective, as it guarantees the market presence of those treatments that would no longer be profitable for the distributor, resulting probably a product shortage in the absence of preferential status. However, no decision guidance has been issued on the scope of ATC groups and reimbursement categories that could potentially be requested for.
The amount of reimbursement that can be requested under the category of preferential status is not detailed in the legislation, failing that, the 32/2004. (IV. 26.) ESzCsM Decree, Annex 1 will be relevant on this issue.

For a period of 5 years, the NEAK concludes a cap-based price-volume agreement (PVA) for the turnover of medicinal products approved for subsidies with preferential status, limiting their reimbursement outflow at the ex-factory price. According to the previous legislation, this meant that the turnover of the reimbursed medicine (with preferential status) was not allowed to exceed HUF 30 million at the manufacturing price, but based on the amendment that came into force in June 2021, this threshold was raised to HUF 100 million, thus increasing the demand to obtain the status. This specified threshold is a theoretical limit, the maximum amount may vary depending on the number of patients and the price.

In addition to the obvious positive aspects of the status, limited information is available on the practical implementation, as the published list of the reimbursement procedures does not clarify all cases where an application for preferential status has been made, thus the exact number of applications processed and the evaluation criteria are not available in detail.

As an example, an application of an analgesic medicinal product was submitted twice for preferential reimbursement status in the indication point EÜ100, but both of them were rejected. Only one formulation has been approved for this status since 2014, an anti-arrhythmic medication containing propafenone in the Normative 0 reimbursement category, as a hospital drug. At the time of this drug's preferential status application procedure, 3 other brands with the same active ingredient were included in the active substance-based fixed group, but with different pharmaceutical forms (formulas already got reimbursement: film-coated tablets, formula with a preferential status request: solution for injection), this may contribute to market uniqueness that the drug became the only product obtaining the preferential status. However, the cap-based PVA at ex-factory price is not relevant for this product due to its reimbursement category (Norm 0), as it does not generate reimbursement outflow, – does not receive a tax allowance either –, and does not appear on the published list of drugs with PVAs.

In 2014, when the preferential status as a reimbursement method was introduced, a medicinal product could only be approved for obtaining the status with the expert opinion of the National Pharmaceutical Council (OGYTT). The operation of the Council at that time was uncertain, its members were unknown, and the place and frequency of meetings were not available to the public. After the June 2021 legislative amendment, by simplifying processes, the Council's expertise will no longer be necessary to assess preferential status, NEAK will have the right to decide on the applications after an approval by the Minister of Health.

[1]Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products

Preferential status — Case study

Healthware analysis based on NEAK data

With regards to the legislative amendment of Gyftv., apparently the decision-makers seek to simplify the conditions of the subsidy approval procedures for beneficiary status (increasing the CAP in the admission procedure, termination of OGYTT expertise). From the funder's viewpoint, the amendment to the legislation may have been facilitated by the recognition of the possibility that medicinal products that have had reimbursement with preferential status may serve unique patient needs in the market. However, the decision-making criteria and the number of applications considered are unclear, as well as the exact definitions. For example, if two products have the same route of administration, but one can also be administered by another route, whether this different route of administration justifies the uniqueness of the formulation. A further issue may be whether the product with preferential status will appear in the list of drugs having PVAs and how will the review of those products considered as preferred take place in practice (eg whether a cost- effectiveness analysis will be carried after the expiry of the 5-year contract)? The evaluation criteria have been remained unclear, but by making decision-making processes more focused and clarifying the above-mentioned elements, the preferential status may become more attractive to those MAHs having unique medicines to obtain the status, thus providing real therapeutic benefits to patients.