HEALTHWARE

Newsletter
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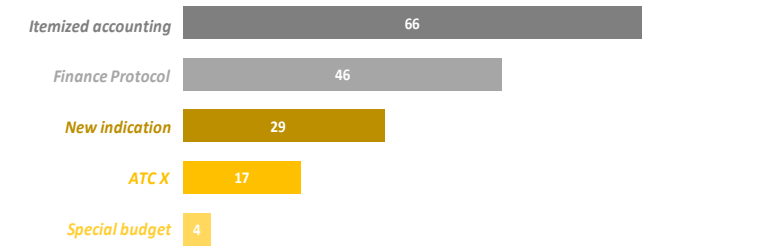
Analysis of innovative reimbursement submissions

Our special edition focuses on those new, mainly innovative pharmaceutical technologies, which were proposed for legislation amendment, therefore NHIFA[1] cannot decide on its own competence. The analysis was based on the information contained in the list of reimbursement submissions, regularly published by NHIFA. *

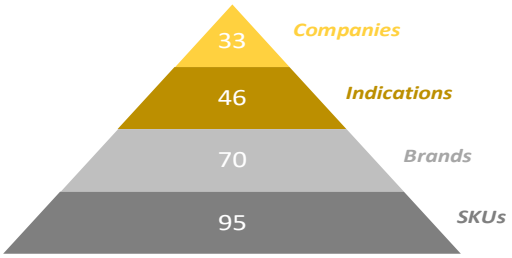
After the change of legislation in 2018, the analysis of a submission's timeline faces many obstacles, since these procedures have to be closed within 360 days. In the case of submissions that appear to exceed this procedure time, companies tend to initiate the closure of the process and resubmitting the dossiers without any, or with minimal changes. In our analysis, the requests closed by a termination order and submitted again within a few months were considered as a re-submission. In the case of these products, the submission date was determined based on the first submission.

* In this analysis we have used the information that was published on 31st of May, 2021 by NHIFA.

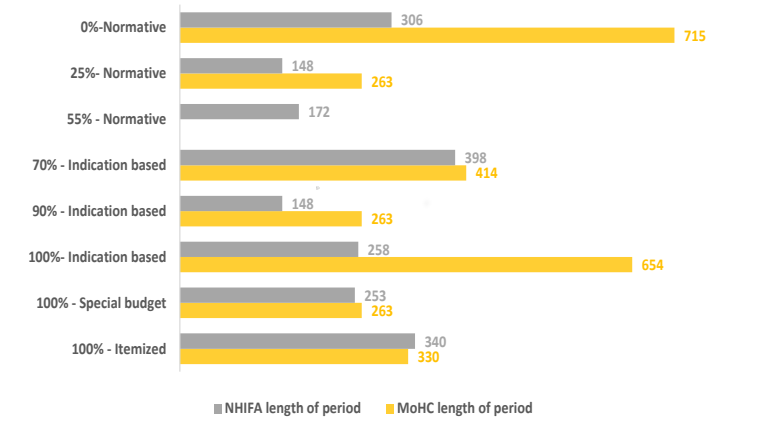
Submissions by type of legislation amendment



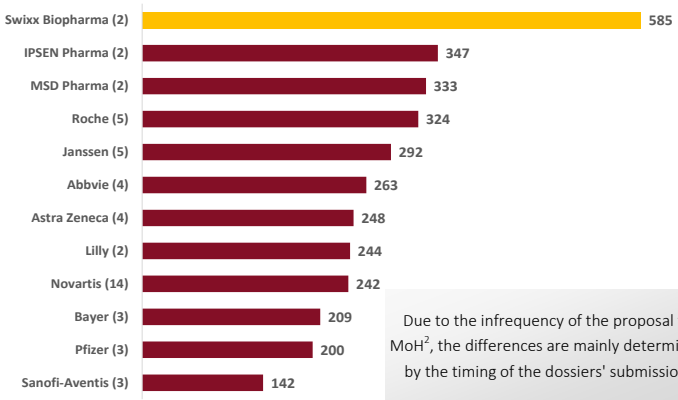
Number of submissions



Average procedure length by reimbursement category (days)

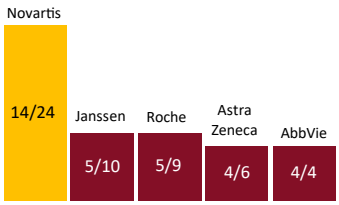


Average of days passed at NHIFA by companies (*brands*)

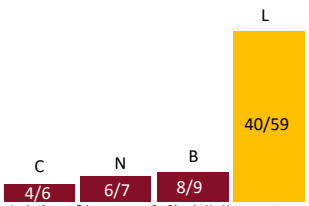


Due to the infrequency of the proposal to MoH[2], the differences are mainly determined by the timing of the dossiers' submission.

Top 5 applicants by the number of brands and applications (*brands/applications*)

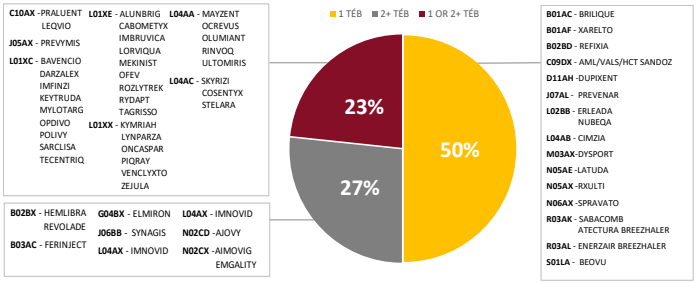


Top 4 ATC main group by the number of brands and TTTs (*brands/TTTs*)



L - Antineop. & immonomo.; B - Blood.; N - Nervus system; C-Cardiovascular

Number of TÉB[3] sessions by ATC5 groups



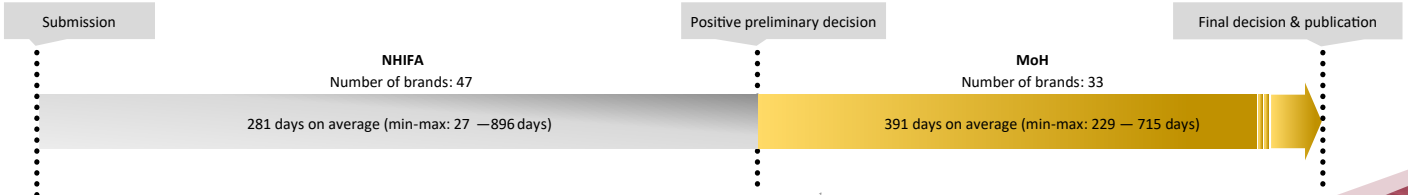
Actual timelines of ongoing procedures are the following:

- Average time between (atb) submission and proposal to the TÉF[4] is 10 days (min. 0 days, max. 27)
- Atb. the handover to TÉF and the first TÉB session takes 93 days (min. 22, max. 163)
- atb. first and last TÉB session is 217 days (min. 36, max. 833)
- atb. last TÉB session and proposal to MoH is 172 days (min.19, max. 408)

NHIFA proposes legislation amendment requests intermittently to the Minister responsible for Health Insurance - in line with the TÉB decision -, based on 2006. Act XCVIII. [Gyftv.], according to which reimbursement of pharmaceutical applications or alteration of reimbursement conditions of an already reimbursed medicine requires amendment of legislation.

Transparent traceability of submissions of pharmaceuticals lasts from the moment of submission till the NHIFA proposal to the Ministry. Thereafter, public information is not available regarding the decisions until the publication of the bulletin.

With further questions, please contact us!



[1] NHIFA: National Health Insurance Fund of Hungary
[2] MoH: Ministry of Health; officialy
[3] TÉB—Technológia-Értékelő Bizottság, Tech. Appraisal Committee
[4] TÉF—Technológia-Értékelő Főosztály, Tech. Appraisal Dept.

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