HEALTHWARE

Newsletter
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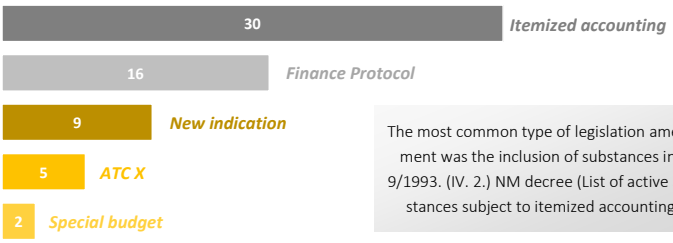
Analysis of the transparent submission procedures of products proposed to MOH decision

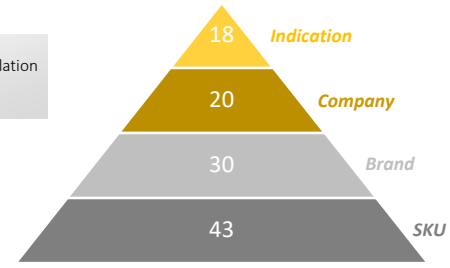
Our special edition focuses on those new, mainly innovative pharmaceutical technologies, which were proposed for legislation amendment by the National Health Insurance Fund of Hungary (NHIFA) to the Ministry of Health (MoH[1]) on 11 September, 2020. In case of those pharmaceuticals, where the amendment of legislation is necessary, NHIFA cannot decide on their own. Submissions are sent to the MoH[1] intermittently, where the final decisions are made.

Submissions by type of legislation amendment[2]

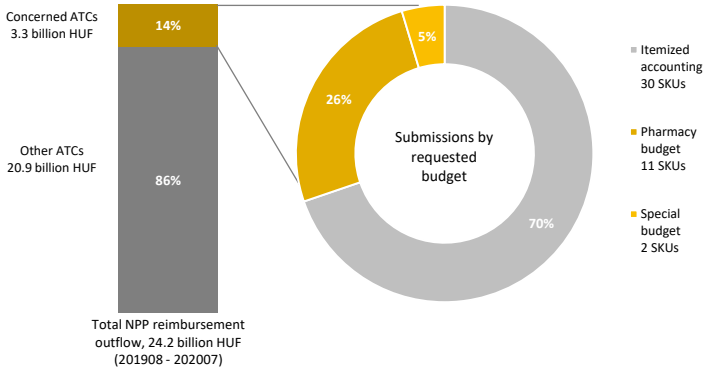


The most common type of legislation amendment was the inclusion of substances into 9/1993. (IV. 2.) NM decree (List of active substances subject to itemized accounting).

43 SKUs were proposed to legislation amendment



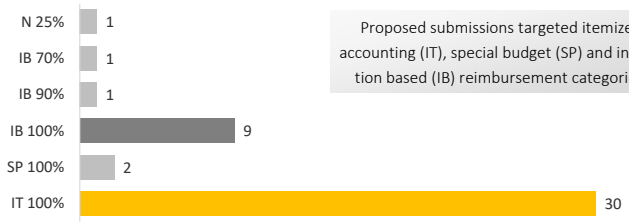
MAT NPP reimbursement of the concerned ATCs and number of submissions by budget[2]



Number of the ongoing submission procedures by ATC5 codes[2]

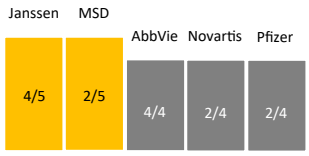
ATC5	Name	Brands	SKUs
L01XE	Protein kinase inhibitors	5	9
L01XC	Monoclonal antibodies	4	9
L04AA	Selective immunosupressants	3	4
C10AX	Other lipid modifying agents	2	3
B02BD	Blood coagulation factors	2	2
L01XX	Other antineoplastic agents	2	2
L04AC	Interleukin inhibitorok	2	2
J05AX	Other direct acting antivirals	1	2
R07AX	Other respiratory system products	1	2
L02BB	Anti-androgens	1	1
L04AB	Tumor necrosis factor alpha (TNF-α) inhibitor	1	1
L04AX	Other immunosuppressants	1	1
R03AK	Adrenergics in combination with corticosterc	1	1
J06BB	Specific immunoglobulins	1	1
V10XX	Various therapeutic radiopharmaceuticals	1	1
B01AC	Platelet aggregation inhibitors excl. Heparin	1	1
N05AE	Indole derivatives	1	1
Total		***30***	***43***

Number of submitted SKUs by requested reimbursement category[2]

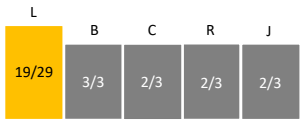


Proposed submissions targeted itemized accounting (IT), special budget (SP) and indication based (IB) reimbursement categories.

Top 3 applicants by the number of brands and SKUs[2]



Top 3 ATC main group by the number of brands and SKUs[2]



L - Antineop. & immunomo.; C - Cardiovascular; B - Blood; R - Respiratory; J - Antiinfections

Since the change of legislation in 2018, the analysis of a submission's Timeline faces many obstacles. In the lack of public information, it is not clear whether a resubmission has relevant change in content in contrast to the former submission. In order to get realistic results in the Timeline analysis, only those submissions were taken into account where all the needed information (date of the HTA Body "TÉF[3]" and Technology Appraisal Committee "TÉB[4]" session) is available.

On the Timeline the last TÉB session are shown. However, several TÉB[4] session may take place till the final decision. According to these submissions,

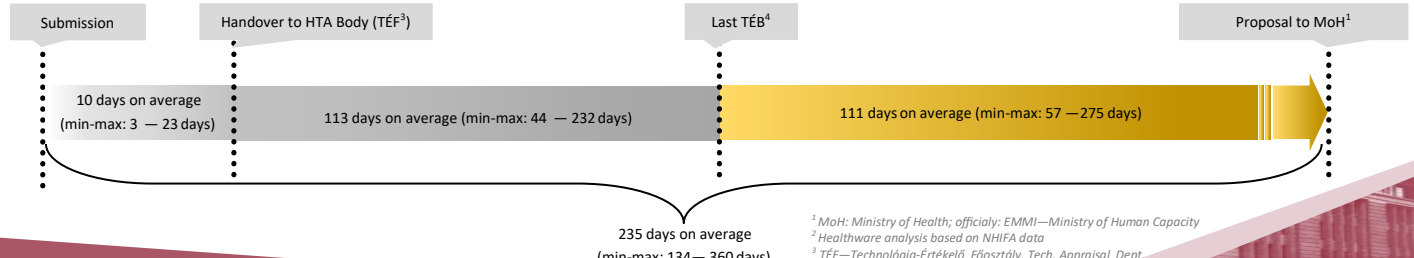
- average time between (atb) submission and proposal to the TÉF[3] is 10 days (min. 3 days, max. 23)
- atb. the handover to TÉF[3] and the TÉB[4] session takes 113 days (min. 44, max. 232)
- atb. first and last TÉB[4] session is 73 days (min. 28, max. 155)
- atb. last TÉB[4] session and proposal to MoH[1] is 111 days (min. 57, max. 275)
- atb. submission and proposal to MoH[1] takes 235 days (min. 134, max. 360)

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.

The last time the NHIFA sent a proposal to MoH[1] was more than a year ago, on June 17, 2019. After the proposal, the final decision of reimbursement submissions shall be made by a Committee assigned by Government decree 452/2017. (XII. 27.).

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] MoH: Ministry of Health; officialy: EMMI—Ministry of Human Capacity
[2] Healthware analysis based on NHIFA data
[3] TÉF—Technológia-Értékelő Főosztály, Tech. Appraisal Dept.
[4] TÉB—Technológia-Értékelő Bizottság, Tech. Appraisal Committee

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