

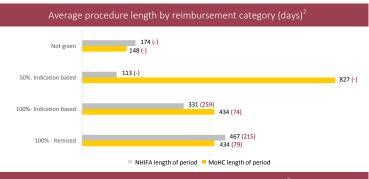
## Analysis of the ongoing submission procedures

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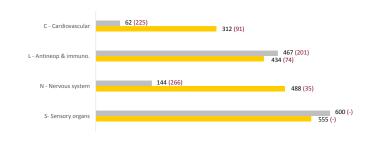
This analysis examines the new, typically innovative pharmaceutical technologies that have been submitted but do not yet make the final decision by the National Health Insurance Fund of Hungary (NHIFA) and Ministry of Human Capacities (MoHC). This special edition has been updated with the 9 month event since the <u>previous</u> report. The previous marked in red are also represented to make the changes clear visible. The analysis focuses only on the technologies that passed the standard 90 days period and bases on the data published by the NHIFA on April 09, 2020. The validity of published data has not been investigated by Healthware.

## Number of the ongoing submission procedures by reimbursement category (brands)<sup>2</sup>





Average procedure length by ATC main groups (days)<sup>2</sup>



NHIFA length of period MoHC length of period



During the NHIFA co-ordinated period, the financing structure for the technology will be determined on the basis of submitted and agreed HTA, BIA and medical considerations. The final decision is taken by a Committee coordinated by the Ministry. Actual timelines of ongoing procedures are the following:

- NHIFA made a preliminary decision on 7% of the normal submissio
- The average procedure time of the analyzed products is 273 days in case of normal submission (min-max: 101 and 1155 days) and 224 days (min-max: 101 and 531 days) when simplified submission.
- The average procedure time of NHIFA is 342 days in case of normal submission (min-max: 62 and 600 days) and 174 days when simplified submission



## Number of the ongoing submission procedures by ATC5 codes<sup>2</sup>

| ATC5  | Name   | Brands | SKUs |
|-------|--|--------|------|
| L01XC | Monoclonal antibodies  | 6      | 16   |
| L01XE | Protein kinase inhibitors  | 6      | 12   |
| V06D  | Other nutrients  | 3      | 3    |
| B01AB | Heparin group  | 2      | 7    |
| B02BD | Blood coagulation factors  | 2      | 2    |
| L04AC | Interleukin inhibitors   | 2      | 2    |
| N07XX | Other nervous system drugs   | 2      | 4    |
| A05AA | Bile acids and derivatives   | 1      | 1    |
| A10AB | Insulins and analogues for injection, fast-acting                                      | 1      | 2    |
| A10BD | Combinations of oral blood glucose lowering drugs                                      | 1      | 1    |
| B01AC | Platelet aggregation inhibitors excl. heparin  | 1      | 1    |
| B01AF | Direct factor Xa inhibitors  | 1      | 1    |
| B02BX | Other systemic hemostatics   | 1      | 1    |
| C03XA | Vasopressin antagonists  | 1      | 1    |
| C09CA | Angiotensin II receptor blockers (ARBs), plain   | 1      | 2    |
| C09DA | Angiotensin II receptor blockers (ARBs) and diuretics                                  | 1      | 3    |
| C10AX | Other lipid modifying agents   | 1      | 1    |
| D11AH | Agents for dermatitis, excluding corticosteroids                                       | 1      | 1    |
| G04BX | Other urologicals  | 1      | 1    |
| J05AX | Other direct acting antivirals   | 1      | 2    |
| J06BB | Specific immunoglobulins   | 1      | 1    |
| L01   | ANTINEOPLASTIC AGENTS  | 1      | 2    |
| L01CD | Taxanes  | 1      | 1    |
| L01XX | Other antineoplastic agents  | 1      | 1    |
| L02BB | Anti-androgens   | 1      | 1    |
| L04AA | Selective immunosuppressants   | 1      | 2    |
| L04AB | Tumor necrosis factor alpha (TNF-α) inhibitors   | 1      | 1    |
| L04AX | Other immunosuppressants   | 1      | 1    |
| M05BX | Other drugs affecting bone structure and<br>mineralization                             | 1      | 1    |
| N02   | ANALGESICS   | 1      | 1    |
| N03AA | Barbiturates and derivatives   | 1      | 1    |
| N03AX | Other antiepileptics   | 1      | 2    |
| N05AE | Indole derivatives   | 1      | 1    |
| N06BA | Centrally acting sympathomimetics  | 1      | 7    |
| N07BA | Drug used in nicotine dependence   | 1      | 1    |
| R03AK | Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics | 1      | 1    |
| S01XA | Other ophthalmologicals  | 1      | 1    |
| V10XX | Various therapeutic radiopharmaceuticals   | 1      | 1    |
| Total |  | 54     | 91   |

The average procedure time of MoHC is 512 days in case of normal submission (min-max: 312 and 827 days).

• 54 brands are waiting for ministerial decision at the moment.

Typically the average waiting time is longer in case of products which claimed changes in legislation and which are innovative products with new mode of action (e.g. PCSK9 inhibitors, targeted oncology therapies, immuntherapies). The most frequent indications are the neoplastic diseases and within that the colitis ulcerosa and the non -small cell lung cancer.

|                    |  |                               |  | nurfurther questions, pieuse contact us: |  |
|--------------------|--|-------------------------------|--|--|--|
| Submission         |  | Positive preliminary decision |  | Final decision & publication             |  |
| :                  | NHIFA <sup>1</sup>   |                               | MoHC1  | ÷  |  |
|                    | 342 days on average (min-max: 62 — 600 days)<br>221 days on average (min-max: 24 — 605 days) |                               | 512 days on average (min-max: 312 —827 days)<br>87 days on average (min-max: 36—279 days)  |  |  |
|                    |  |                               |  |  |  |
| 0. day             | 90. day <sup>3</sup>   | 250. day                      |  | 270. day                                 |  |
|                    |  | <sup>2</sup> /                | NHIFA: National Health Insurance Fund of Hungary<br>Healthware analysis based on NHIFA data<br>Standard official process period of NHIFA |  |  |
| are Consulting Ltd |  |                               |  |  |  |

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