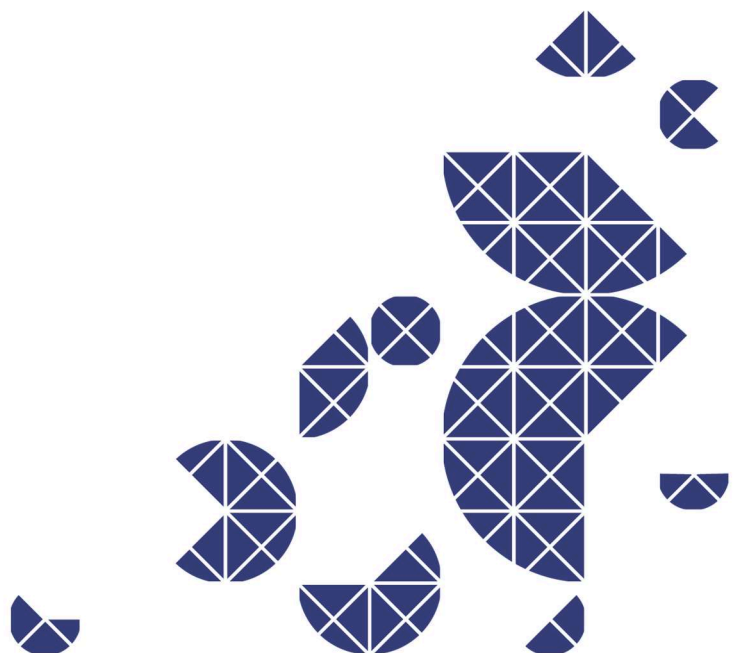


# **National Institute for Value and Technologies in Healthcare**

## **2022 Annual Report on the Activities of the Institute**

**Published on: 23 May 2023**



## CONTENTS

|  |    |
|--|----|
| CONTENTS.....  | 2  |
| SPEECH OF THE DIRECTOR.....  | 3  |
| 1. IDENTIFICATION OF THE ORGANISATION.....                             | 4  |
| 2. BODIES OF THE INSTITUTE.....  | 5  |
| 3. ABOUT THE INSTITUTE.....  | 6  |
| 4. ACTIVITIES OF THE INSTITUTE.....                                    | 7  |
| 4.1. Professional Assessments.....                                     | 7  |
| 4.1.1. Assessments Started in 2022.....                                | 7  |
| 4.1.2. Published Protocols.....  | 9  |
| 4.1.3. Published Assessments.....                                      | 9  |
| 4.2. Savings for the Public Health Insurance.....                      | 10 |
| 4.3. Other Tasks.....  | 11 |
| 4.4. Methodological Issues.....  | 11 |
| 4.5. Cooperation in Slovakia.....                                      | 11 |
| 4.6. International Cooperation.....                                    | 12 |
| 4.7. Publishing.....   | 14 |
| 5. REPORT ON FINANCIAL MANAGEMENT FOR 2022.....                        | 15 |
| 5.1. BUDGET OF THE INSTITUTE.....                                      | 15 |
| 5.1.1. Revenues.....   | 15 |
| 5.1.2. Expenditures.....   | 15 |
| 5.2. Assets, Own Capital and Payables.....                             | 16 |
| 5.3. Auditor's opinion.....  | 17 |
| 5.4. Management of the Institute.....                                  | 17 |
| 6. HUMAN RESOURCES.....  | 18 |
| 7. KEY PERFORMANCE INDICATORS AND FULFILMENT THEREOF.....              | 20 |
| 8. ANALYSIS OF DEVELOPMENT OF THE INSTITUTE.....                       | 21 |
| Annex No. 1: Approved financial statements as at 31 December 2022..... | 22 |

## SPEECH OF THE DIRECTOR

Dear ladies and gentlemen,

The National Institute for Value and Technologies in Healthcare (also known as NIHO) has successfully completed its first busy year, full of intensive work. Our task was to build a public institution from the scratch in all fields: personnel, professional or material and technical. We have grown from 5 to 23 employees, reaching our full capacity of staff. We cover a broad spectrum of expertise as a result of a challenging selection process in economics, mathematics, pharmacology, medicine and more. Thanks to great effort and international cooperation, we managed to add NIHO onto the map of well-developed HTA institutions.

A big thank you goes out to all my colleagues and all our partners in the sector, who have supported us during this challenging period. As a result of 14 assessments completed in 2022 in cooperation with the Ministry of Health of the Slovak Republic, we already managed to generate savings for the public health insurance in the amount exceeding EUR 50 million.

However, even more important was to build the internal culture of the institution in order to ensure that our contribution will be continuous in the long term. To my great delight, we also managed to fulfil this important goal, and at NIHO, we are all very aware of our key role in the efficient and transparent management of a limited budget for healthcare technologies, with the aim to provide the best possible healthcare for the patients in Slovakia.

In this manner, we have launched an institution in accordance with the European standard, set



up the necessary processes and fully complied with our statutory tasks. We have involved all relevant stakeholders in the process and we publish all our work for the purpose of public scrutiny, thus making the reimbursement process more legitimate and transparent. I believe that we have managed to create excellent preconditions essential for stable fulfilment of NIHO's primary task, which is to assess technologies applying for reimbursement in the Slovak Republic in a professional manner.

Ahead of us is a period of stabilisation and further professional growth, which we look forward to. Details on the past year of our institute can be found below in this annual report.

**MA. Michal Staňák, Dr.phil, AKC**  
Managing Director/CEO of NIHO



## 1. IDENTIFICATION OF THE ORGANISATION

**Name of the organisation:**

Národný inštitút pre hodnotu a technológie v zdravotníctve (National Institute for Value and Technologies in Healthcare)

**Registered office of the organisation:**

Zámocké schody 2/A, 811 01 Bratislava

**Identification No.:**

54 343 461

**Phone number:**

+421 911 652 357

**E-mail address:**

kancelaria@niho.sk

**Website:**

[www.niho.sk](http://www.niho.sk)

**Legal form:**

other public administration organisation, established by Act No. 358/2021 Coll.

**Statutory representative:**

MA. Michal Staňák, Dr.phil, AKC, Managing Director/CEO

The National Institute for Value and Technologies in Healthcare (hereinafter as “NIHO”) hereby submits the 2022 Annual Report on the Activities of NIHO. NIHO is an independent, separate legal entity established by Act No. 358/2021 Coll., and therefore is not part of the Ministry of Health of the Slovak Republic’s budget chapter. In its activities, NIHO acts in accordance with the Act on NIHO (No. 358/2021 Coll.), Act No. 552/2003 Coll. on carrying out work in the public interest, the Labour Code and other regulations laying down the obligations of public administration authorities.

## 2. BODIES OF THE INSTITUTE

### Managing Director/CEO

**MA. Michal Staňák, Dr.phil, AKC**, Managing Director/CEO, in the office since 1 January 2022

### Supervisory Board

**Ing. Martin Vlachynský**, Chairman of the Supervisory Board nominated by the Ministry of Health of the Slovak Republic

**Ing. Vladimír Turček, PhD.**, Member of the Supervisory Board nominated by the Ministry of Finance of the Slovak Republic until 14 October 2022

**Ing. Peter Magát**, Member of the Supervisory Board nominated by the Ministry of Finance of the Slovak Republic since 15 October 2022

**Ing. Marcel Mikolášik**, Member of the Supervisory Board nominated by the Association of Health Insurance Companies

**Mgr. Adam Markuš**, Member of the Supervisory Board nominated by NIHO employees

### Scientific Advisory Board

#### **Chris McCabe, BA (Hons), MSc, PhD.**

Professor of Health Economics at the Queen's University Belfast, former CEO of the Canadian Institute of Health Economics

#### **Claudia Wild, Priv.-Doz. Dr. phil.**

CEO of AIHTA, the Austrian HTA institution, and of its predecessor, LBI-HTA

#### **Martin Višňanský, MBA, PhD., MSc.**

Co-founder and president of the Slovak Society for Pharmacoeconomics (SLS) and co-founder of the Slovak Agency for Health Technology Assessment

#### **Lars Sandman, prof.**

Director of the National Centre for Priorities in Health and professor at the Linköping University, Sweden

#### **Wija Oortwijn, PhD.**

President of the international organisation Health Technology Assessment International and a researcher at the Radboud University, Netherlands

### 3. ABOUT THE INSTITUTE

NIHO is an independent national HTA (Health Technology Assessment) institution that carries out assessment of healthcare technologies. NIHO performs the role of an advisory body of the Ministry of Health of the Slovak Republic (the “MoH”), which entrusted the institute primarily with advisory-related tasks connected with the assessment of expensive healthcare technologies entering into the list of technologies reimbursed by public health insurance (“PHI”), so called categorization list. Despite the fact that in addition to medicinal products (i.e. medicines), the concept of “healthcare technology” also includes medical aids, material or equipment, the majority of NIHO’s assessments is focused precisely on medicinal products. It is primarily medicinal products that meet the condition of high budget impact (in accordance with Section 3 (1) of Act No. 358/2021 Coll.) The assessment process takes 130 days (excluding interruptions) and the primary output of NIHO’s work is the creation of assessments, the conclusion of which is a recommendation for the MoH whether a new technology should be reimbursed from the public resources or not.

In its work, NIHO applies internationally established and transparent procedures pursuant to evidence-based medicine, and actively cooperates with foreign HTA institutions. NIHO works in a multidisciplinary manner and applies the European EUnetHTA methodology in all its assessments.

NIHO is a legal entity that is not registered in the business register, it is established by special Act No. 358/2021 Coll., and is independent from political institutions or healthcare technology industry. NIHO’s independence is mainly ensured by a transparent selection of the director as well as by a specific manner of financing by health insurance companies, similarly to the financing of another independent institution in healthcare established by law – the Health Care Surveillance Authority.

NIHO’s primary mission is to help the efficient spending of limited resources, i.e. bring value for money in healthcare. Other NIHO’s objectives include assistance with improving the quality of healthcare and bringing transparency to decision-making processes in the healthcare sector, mainly within the categorisation of new technologies (mostly medicines).

## 4. ACTIVITIES OF THE INSTITUTE

### 4.1. Professional Assessments

#### 4.1.1. Assessments Started in 2022

NIHO's main role, which is the assessment of medicinal products applying to enter into categorisation with a high impact on the budget (in accordance with Section 3 (1) of Act No. 358/2021 Coll.), is depicted in detail in the table below (Table 1: List of assessments started in 2022). It is a list of medicinal products that fall under the professional assessment of NIHO, and their estimated impact on the budget for the third year after their inclusion into the List of Categorised Medicinal Products was beyond EUR 2.2 million, which was the set threshold for the year 2022, in accordance with Section 13 (4) of Act No. 358/2021 Coll. The cumulative gross annual impact of medicinal products applying for categorisation in 2022, assessed by NIHO, reached EUR 230 million in the third year after their inclusion.

Table 1: List of assessments started in 2022

| Month of application | Type              | Name     | Number of indications | Scope of assessment             | Status                             |
|----------------------|-------------------|----------|-----------------------|---------------------------------|------------------------------------|
| April 2022           | medicinal product | Darzalex | 3 (4)                 | full                            | completed incl. updating in 2022   |
| April 2022           | medicinal product | Skyrizi  | 1                     | full                            | completed in 2022                  |
| April 2022           | medicinal product | Alunbrig | 2                     | without pharmacoeconomics       | completed incl. updating in 2022   |
| April 2022           | medicinal product | Advate   | 1                     | abbreviated                     | completed in 2022                  |
| April 2022           | medicinal product | Tukysa   | 1                     | without pharmacoeconomics, full | published in 2022, updated in 2023 |
| April 2022           | medicinal product | Nubequa  | 1                     | full                            | completed in 2022                  |
| April 2022           | medicinal product | Leqvio   | 1                     | full                            | completed in 2022                  |
| April 2022           | medicinal product | Fasenra  | 1                     | full                            | completed in 2022                  |
| May 2022             | medicinal product | Kerendia | 1                     | full                            | completed in 2022                  |
| May 2022             | medicinal product | Spravato | 1                     | full                            | completed in 2022                  |

|                |                   |           |   |          |                                 |
|----------------|-------------------|-----------|---|----------|---------------------------------|
| June 2022      | medicinal product | Cibinqo   | 1 | full     | completed in 2022               |
| June 2022      | medicinal product | Opdivo    | 2 | full     | completed as at 04/2023         |
| June 2022      | medicinal product | Crysvita  | 2 | N/A      | Application rejected by the MoH |
| July 2022      | medicinal product | Kisqali   | 3 | full     | completed as at 04/2023         |
| July 2022      | medicinal product | Vyndaqel  | 1 | full     | completed as at 04/2023         |
| July 2022      | medicinal product | Ibrance   | 3 | full     | completed as at 04/2023         |
| July 2022      | medicinal product | Xtandi    | 3 | full     | completed as at 04/2023         |
| July 2022      | medicinal product | Tafinlar  | 1 | full     | completed as at 04/2023         |
| July 2022      | medicinal product | Mekinist  |   | full     | completed as at 04/2023         |
| August 2022*   | medicinal product | Verzenio  | 3 | full     | completed as at 04/2023         |
| August 2022    | medicinal product | Ofev      | 2 | full     | completed as at 04/2023         |
| August 2022    | medicinal product | Epclusa   | 1 | full     | completed in 2022               |
| August 2022    | medicinal product | Kymriah   | 2 | full     | completed as at 04/2023         |
| August 2022    | medicinal product | Hemlibra  | 2 | full     | completed as at 04/2023         |
| September 2022 | medicinal product | Yescarta  | 1 | full     | completed as at 04/2023         |
| September 2022 | medicinal product | Evusheld  | 1 | full     | completed as at 04/2023         |
| September 2022 | medicinal product | Ondexxya  | 1 | partial* | completed as at 04/2023         |
| September 2022 | medicinal product | Tecentriq | 4 | full     | completed as at 04/2023         |
| October 2022   | medicinal product | Polivy    | 1 | full     | completed as at 04/2023         |



|               |                   |           |   |      |                         |
|---------------|-------------------|-----------|---|------|-------------------------|
| October 2022  | medicinal product | Keytruda  | 1 | full | completed as at 04/2023 |
| October 2022  | medicinal product | Zolgensma | 2 | full | completed as at 04/2023 |
| October 2022  | medicinal product | Lynparza  | 3 | full | in progress             |
| October 2022  | medicinal product | Enhertu   | 1 | full | in progress             |
| November 2022 | medicinal product | Vydura    | 1 | full | in progress             |
| November 2022 | medicinal product | Imbruvica | 1 | full | in progress             |
| November 2022 | medicinal product | Keytruda  | 1 | full | in progress             |
| November 2022 | medicinal product | Tagrisso  | 2 | full | in progress             |
| December 2022 | medicinal product | Lumykras  | 1 | full | in progress             |
| December 2022 | medicinal product | Epidyolex | 2 | full | in progress             |

\* the assessment of the Ondexxya medicinal product was partial due to the fact that within the assessment process, NIHO identified that the given medicinal product does not belong to the list of categorised medicinal products for outpatient care, but for inpatient care, and since it does not fall within the definition of an innovative medicinal product, it cannot be categorised.

#### 4.1.2. Published Protocols

For each technology assessed, NIHO first prepares a project protocol, which defines the research question of the professional assessment in question, the method of solution thereof and the time frames. The protocols to the assessments in progress are published on the NIHO's website (see <https://niho.sk/rozpracovane-projekty/>) and on the categorisation portals. In case that an assessment is already published, it is moved from the "Projects in progress" subpage to the "Published projects" page, together with all relevant document for the assessment in question (see <https://niho.sk/publikovane-projekty/>).

#### 4.1.3. Published Assessments

Until the end of 2022, 15 assessments and 6 updates were completed, while as at the end of April 2023, further 33 assessments and 1 update have been completed. From the end of 2022, 12 assessments remained in progress.

## 4.2. Savings for the Public Health Insurance

The estimated amount of savings reached in 2022 within 15 NIHO's assessments (11 medicinal products in 14 indications) represented EUR 52.9 million. Such savings were reached by joint effort of the MoH and the NIHO, while NIHO's assessments serve as background documents for the Ministry in negotiations over the coverage with the marketing authorisation holder of the respective medicinal product. These savings remain in the PHI's budget and can be used to improve the health of patients in Slovakia. In practice, this means that in 2022, even the more expensive medicinal products were included in the categorisation, which will contribute to the improvement of health of patients in Slovakia. Thanks to NIHO's assessment, within the negotiations with the MoH, the marketing authorisation holders of such medicinal products offered a sufficient discount in order to comply with the conditions of cost-effectiveness laid down in Section 7 (2) of Act No. 363/2011 Coll.

The estimated savings are calculated from the sum of impacts on the PHI's budget for the following five calendar years after the inclusion of the medicinal product, in their desired indications, in the categorisation list. The calculation used the difference in the impact on the budget with coverage per one package of the medicinal product, for which the marketing authorisation holder applied, and which was agreed in the Managed Entry Agreement. It is a conservative estimate of savings for the PHI for the following reasons:

- The savings will remain even after the first five years, but, conservatively, the savings for the sixth and each following year were not included.
- With certain medicinal products, a cap for the total coverage was agreed, which is lower than the coverage agreed in the Managed Entry Agreement per one package of the medicinal product multiplied by the estimated number of packages consumed. Therefore, as a result, the impact will be even lower than the number used in the calculation of the estimated savings.
- Neither of NIHO's assessments included in the savings analysis were necessarily negative (all included assessments recommended a higher discount than the one proposed by the marketing authorisation holder in the application).
- The savings were not calculated in the given estimate, if the MoH arranged even a lower coverage than the one recommended by NIHO.

The given estimate is optimistic in the aspect that price erosion was not taken into account, which, based on external referencing, reduces the price of medicinal products by a few percent year over year. However, we believe that the above-mentioned conservative aspects of the estimated savings predominate significantly.

In the elaboration of the Act on NIHO, the impact study calculated with estimated savings caused by NIHO at the level of EUR 5 million per year (EUR 25 million cumulatively in 5 years). With the expenditures for NIHO's activity of approximately EUR 1.6 million, this represented 15-times return on

investment. However, in the first year of its operation, the work of NIHO (together with the MoH) generated more than 40-times return on investment.

The assessment of the inclisiran pharmaceutical serves as an example. In this assessment, NIHO correctly identified multiple problems in setting the coverage terms and prescribing practices of the pharmaceuticals for lowering cholesterol (which did not comply with European recommendations). After consulting with the MoH and the Slovak Cardiological Society, the problems identified in the application for categorisation were modified, the indication limitation of the substituted effective therapy by established pharmaceuticals was changed, and new coverage terms were agreed with the marketing authorisation holder. Thanks to NIHO's contribution, the treatment of cholesterol for patients in Slovakia was aligned with international standards, under sustainable financial terms negotiated by the MoH based on NIHO's assessment.

#### **4.3. Other Tasks**

Beyond the primary task of assessing forthcoming expensive medicinal products, in the 1st quarter 2022, NIHO, in cooperation with the Division of Pharmacology and Drug Policy of the MoH, prepared an estimate of the impact of the amendment to Act No. 363/2011 Coll. of 1 August 2022 on the budget.

As a consequence of the amendment to Act No. 363/2011 Coll. of 1 August 2022, in which the level of willingness to pay per one quality adjusted life year (QALY) has significantly increased, the number of applications for categorisation has roughly doubled in comparison with the expectations. For this reason, NIHO's capacities were almost exclusively focused on the main tasks of medicinal products' assessment throughout 2022.

#### **4.4. Methodological Issues**

Throughout 2022, in particular in the first two quarters, considerable capacities of the NIHO's management were invested in setting up the internal processes of assessment, procedures in assessing clinical benefits of pharmaceuticals and pharmacoeconomics.

The NIHO's assessment template is built on questions from the primary European methodological document, the EUnetHTA Core model, while the patient and expert input template is in the structure, in which patients and experts provide inputs for the assessments of the English HTA Institute, the National Institute for Health and Care Excellence.

#### **4.5. Cooperation in Slovakia**

NIHO is an independent public administration institution, which was entrusted by the MoH with the task of assessing expensive technologies (mainly medicinal products) in the categorisation process. In this capacity, in 2022, NIHO was actively setting up cooperation with the relevant division of the MoH,

the Division of Pharmacology and Drug Policy, relating to the sharing of assessments, legislative and sub-legislative standards, communication with the marketing authorisation holders, methodology or deadlines.

At the same time, for the purpose of producing quality assessments, it is required that the patients' organisations and clinical experts are able to provide their inputs into NIHO's assessments. For this reason, in 2022, NIHO established cooperation with patients' organisations, such as Liga proti rakovine (League Against Cancer), Amazonky (The Amazonians), Asociácia na ochranu práv pacienta (Association for the Protection of Patient's Rights) and others. At the same time, NIHO established cooperation with clinical societies, such as the Slovak Oncological Society or the Slovak Cardiological Society.

The reason why NIHO requires the input of the patients' organisations into the assessment is to obtain information about the life with a disease, experience with the diagnostics process, the patient's journey or about the impact of the disease on the social aspects of life. In addition, the input of clinical experts covers the need for information on the substituted treatment or experience of doctors with the assessed treatment in question.

In 2022, NIHO received an input into the assessment from clinical experts in all completed assessments, while the input from the patients' organisations was received in 50% of the assessments.

In other assessments, NIHO used the inputs from the patients that were found in assessments of the given pharmaceuticals in other countries. However, in all assessments, the relevant patients' organisations as well as the clinical experts have been approached.

## 4.6. International Cooperation

### European Structures

Within the assessment of healthcare technologies, the cooperation across the European Union countries has been ongoing since 2006, in which common assessment of technologies as well as unification of methodology is carried out. This cooperation is called the European Network for Health Technology Assessment (EUnetHTA), and before the establishment of NIHO, Slovakia participated in it only partially. In 2021, this cooperation was transformed into the European Regulation 2021/2282 (the so-called HTA Regulation, HTAR), based on which common assessment of medicinal products and medical aids or material will be carried out as of 2025. These are common assessments of exclusively clinical benefit (not other aspects such as assessments of cost-effectiveness of technologies) registered by the European Medicines Agency. As of June 2022, the preparatory phase of setting up the common assessment processes has started, in which NIHO fully participates. Six NIHO employees (together with the MoH employees) are members of individual subgroups for common assessments, scientific consultations, methodology and horizon scanning. As of 2023, the HTAR meetings will take place on a (bi-)monthly basis.

In parallel to the preparatory work in the common European assessment, the NIHO is part of the group of directors of European HTA institutions (the Heads of Agencies Group, HAG), the objective of which is to unify the position of HTA institutions in this preparatory phase of the HTAR implementation. The HAG meetings take place on a quarterly basis.

### **International Organisations**

Along with the participation in the European structures, NIHO is part of international HTA societies, through which NIHO also established itself already in 2022 as a stable partner in international cooperation. Thanks to this cooperation, NIHO is able to build its capacities in an international standard. NIHO is a member institution of the Health Technology Assessment International (HTAi), International Network of Agencies for Health Technology Assessment (INAHTA), and also cooperates with regional partners from the Czech Republic and Hungary. NIHO works with the above institutions on a monthly basis through the membership in working groups, such as:

- INAHTA working group responsible for capacity building and scientific programme,
- INAHTA working group responsible for INAHTA's position towards the "Real world evidence",
- HTAi working group dealing with ethical aspects of HTA assessments,
- Working group organised by ZIN, a Dutch HTA institute, dealing with assessment of pharmacoeconomic models in the R programme,
- Cooperation with Czech and Hungarian HTA institutions at the level of individual assessments according to the needs of the assessors.

As a stable partner in international cooperation, NIHO was also asked to participate in cooperation on the following projects:

- SUSTAIN-HTA project of the Utrecht University, Netherlands, relating to a new methodology for healthcare technology assessment,
- DIAMOND project of the Bocconi University, Italy, relating to harmonisation of methodology for digital healthcare technology assessment,
- Master's programme in Applied Healthcare Economics at the Faculty of Economics and Administration of the Masaryk University in Brno.

At the same time, in 2022, the employees of NIHO participated in various training sessions and conferences abroad for the purpose of capacity building, such as:

- Pharmacoeconomics training by the Czech colleagues from the Institute of Health Economics and Technology Assessment (iHETA),
- Advanced Pharmacoeconomics training by the Austrian colleagues at UMIT Tyrol,
- Advanced Modelling training at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) conference,
- HTAi conference,

- INAHTA congress.

### **Scientific Advisory Board**

Within international cooperation, with the aim to set a high methodological standard, NIHO has established the Scientific Board in accordance with Section 5 (17) of Act No. 358/2021 Coll. Its members are renowned experts in the HTA area from Austria, Sweden, Netherlands and Canada, who paid us a visit in July 2022. The Scientific Board provides support to NIHO in methodological issues in assessments, as well as in strategic issues relating to development of a new HTA institution.

## **4.7. Publishing**

### **Website**

With the aim to comply with statutory obligations relating to transparency of processes of a public institution (publishing of invoices, orders and other documents) and also due to the need of communication through the website with the stakeholders relevant for NIHO, the establishment of a website, including the creation of a visual identity, was a priority. As of June 2022, the website ([www.niho.sk](http://www.niho.sk)) was established.

The website's content includes not only the projects in progress and published projects, or published invoices and orders, but also information about the manner of involving the relevant stakeholders (patients' organisations and professional societies) in the evaluation process. It also contains information of an educational nature, i.e. what HTA means, the role in the decision-making process NIHO has in Slovakia, how the categorisation process works, the tasks of the NIHO, the method of NIHO's work and who the professional partners of the NIHO are.

### **Public Communication**

As of September 2022, NIHO started to communicate the conclusions of its professional activity via press releases sent to the representatives of Slovak media and also via LinkedIn portal. This way, NIHO informs about its activity and brings its assessments closer to the wider public.

## 5. REPORT ON FINANCIAL MANAGEMENT FOR 2022

### 5.1. BUDGET OF THE INSTITUTE

#### 5.1.1. Revenues

In 2022, the Institute received two contributions for its activity (see Table 2 below). The first contribution for activity for 2022 was received in January 2022 in the amount of €1,300,265.88. The second contribution for activity for 2023 was received in December 2022 in the amount of €1,720,471.67, of which €44,531.54 was subsequently returned in January 2023 due to an incorrectly determined amount of contribution paid by the health insurance companies.

#### 5.1.2. Expenditures

Personnel expenditures, including travel allowances represented the largest item of current expenditures. In goods, the largest item was the complete furnishing of office premises as well as computer technology, which were accounted for as low-value assets. Other important expenditures included rental and utilities. Expenditures relating to services mainly comprised of the accounting, wage, tax, auditor, legal, educational and other expenditures. Regular transfers mainly comprised of the memberships in international organisations. Capital expenditures were connected with the network infrastructure and the website creation.

Table 2: Budget of the Institute for 2022 in EUR

|   |                  |
|---|------------------|
| <b>I. Total revenues</b>                                    | <b>3,020,738</b> |
| From health insurance companies                             | 3,020,738        |
| <b>II. Total expenditures</b>                               | <b>741,346</b>   |
| A, Current expenditures                                     | 715,310          |
| Salaries  | 490,628          |
| Goods and services  | 222,299          |
| Regular transfers   | 2,383            |
| B, Capital expenditures                                     | 26,036           |
| <b>III. Transfer to further years</b>                       | <b>2,279,392</b> |
| Balance from 2022   | 558,920          |
| Contribution to the year 2023                               | 1,675,940        |
| Overpayment from the contribution for 2023 (to be returned) | 44,532           |

## 5.2. Assets, Own Capital and Payables

Within the performance of its activity, the Institute achieved the following results, which were recognised in its regular financial statements drawn up as at 31 December 2022 (see Table 3 below). The Managing Director as a statutory and executive body of the Institute approved the financial statements.

Table 3: Assets, own capital and payables for 2022 in EUR

|                                   | Balance as at 31 December<br>2022 |
|-----------------------------------|-----------------------------------|
| <b>A. Fixed assets</b>            | <b>22,657.06</b>                  |
| A.I. Long-term intangible assets  | 5,965.50                          |
| A.II. Long-term tangible assets   | 16,691.56                         |
| A.III. Long-term financial assets | 0.00                              |
| <b>B. Current assets</b>          | <b>2,291,534.46</b>               |
| B.I. Supplies                     | 0.00                              |
| B.II. Long-term receivables       | 8,490.00                          |
| B.III. Short-term receivables     | 3,652.31                          |
| B.IV. Financial accounts          | 2,279,392.15                      |
| <b>C. Accruals</b>                | <b>1,678.02</b>                   |
| C.I. Accrued expenses             | 1,678.02                          |
| C.II. Revenue from future periods | 0.00                              |
| <b>Total assets</b>               | <b>2,315,869.54</b>               |

|   | Balance as at 31 December<br>2022 |
|---|-----------------------------------|
| <b>A. Equity</b>                                      | <b>487,662.24</b>                 |
| A.I. Equity and funds                                 | 0.00                              |
| A.II. Funds created from profits                      | 0.00                              |
| A.III. Unsettled economic outturn from the past years | 0.00                              |
| A.IV. Economic outturn for the fiscal year            | 487,662.24                        |
| <b>B. Payables</b>                                    | <b>152,267.17</b>                 |
| B.I. Reserve  | 33,321.35                         |
| B.II. Long-term payables                              | 716.76                            |
| B.III. Short-term payables                            | 118,229.06                        |
| B.IV. Bank loans and other assistance and credits     | 0.00                              |
| <b>C. Accruals</b>                                    | <b>1,675,940.13</b>               |
| C.I. Accrued expenditures                             | 0.00                              |
| C.II. Short-term deferred revenues                    | 1,675,940.13                      |
| C.III. Long-term deferred revenues                    | 0.00                              |
| <b>Equity, payables and accrual accounts</b>          | <b>2,315,869.54</b>               |



### 5.3. Auditor's opinion

In accordance with the applicable Slovak legal regulations, the National Institute for Value and Technologies in Healthcare has drawn up the financial statements as at 31 December 2022. These financial statements have been certified by a statutory auditor – CCS AUDIT, spol. s.r.o., with registered office at Tomášikova 50/E, 831 04 Bratislava, registered with Business Register of the Bratislava I District Court, Section: Sro, Insert No. 33711/B, Slovak Chamber of Auditors Licence No. 276, with the opinion that the financial statements accurately express the financial situation of the company as at 31 December 2022 in all relevant aspects as well as the result of its economic outturn for the fiscal year that ended on 31.12.2022, in accordance with Act No. 431/2002 Coll. on accounting, as amended.

### 5.4. Management of the Institute

The development of the management in the fiscal year 2022 may be considered to be positive. Since the Institute commenced its activity no earlier than in 2022 and its expenditures were only of a starting nature, the Institute's management, with the approval by the Supervisory Board, has decided that the achieved economic outturn will be used as a source of financing for the future periods.

## 6. HUMAN RESOURCES

As a newly-emerging institution, NIHO started its activities as of 1 January 2022 with 4 researchers including the managing director + 1 administrative-technical-supporting worker. From 1 September 2022 until the end of the year, the Institute employed 18 employees, of which 15 were assessors, 2 administrative workers and 1 director (see Table 4).

In the hiring procedure, more than 350 curricula vitae were processed, which resulted in concluding employment contracts with 15 employees. The main channels for seeking human resources were the MoH Facebook page before the end of 2021, the Growni portal and a repeated campaign on profesia.sk portal.

Contracts with other 5 employees were signed at the end of 2022, who will start employment throughout 2023. This way, NIHO came closer to reaching its full staffing capacity.

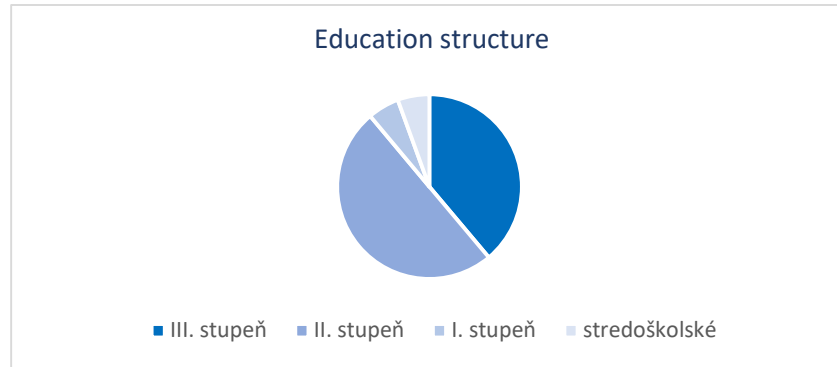
The candidates for the Researcher job position underwent a 4-round selection procedure comprising of the following rounds:

1. Selection based on the curriculum vitae and cover letter.
2. Tests of critical thinking, comprehension and production of an English text, comprehension of a Slovak text.
3. Elaboration of a separate model assessment.
4. Personal interview.

*Table 4: Development of the number of employees in 2022*

|                            | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |
|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| <b>Number of employees</b> | 6   | 5   | 5   | 7   | 7   | 9   | 11  | 15  | 18  | 18  | 18  | 18  |
| <b>of which women</b>      | 2   | 1   | 1   | 3   | 3   | 5   | 5   | 7   | 8   | 8   | 8   | 8   |

The educational background of employees covers various fields, from economics, mathematics, pharmacology, molecular biology, biochemistry, biomedical physics, immunology, medicine to bioethics. One half of the employees has completed the third degree of university education.



The new employees have undergone the training procedure, which is crucial for NIHO, since the majority of the new candidates had not worked particularly in the field of healthcare technology assessment. Therefore, NIHO has prepared a detailed manual with numerous attachments: documents, videos and articles with comments, and/or with a training pharmacoeconomic model. After the initial training month, an employee should understand:

- The principles of evidence-based medicine and work with clinical data
- The opportunity cost principle
- The categorisation in the Slovak Republic and its legislative framework
- The basics of pharmacoeconomics and work with pharmacoeconomic models

After completing the first month, the training procedure continues with the work on a particular assessment in a close cooperation with a superior.

## 7. KEY PERFORMANCE INDICATORS AND FULFILMENT THEREOF

As the only public administration institution, NIHO has the key performance indicators (KPIs) defined in Decree No. 284/2022, laid down in Section 10 (5) of Act No. 358/2021 Coll. The fulfilment thereof is linked to the amount of contribution to NIHO; the first period to which the KPIs apply to, is the year 2023. Despite the first starting year 2022 was omitted from NIHO's obligation to meet the KPIs, all KPIs established by the decree have been met in full. These are:

- a) number of assessments,
- b) compliance with assessment deadline,
- c) content of assessment,
- d) inclusion of reasoning in the assessment,
- e) transparency of assessment,
- f) involvement of professional societies,
- g) involvement of patient organisations.

As per points a), b) and c), NIHO elaborated all assessments that fall within its main task pursuant to Section 3 (1), and in all elaborated assessments, it complied with the statutory deadline in accordance with Section 3 (2) and included in the assessment all assessment aspects defined in Section 2 (b) of Act No. 358/2021 Coll.

As per points d) and e), all NIHO's assessments contained the reasoning of the professional assessment in accordance with Section 3 (1) of the Act, and all assessments were published on the MoH's categorisation portal as well as on NIHO's website.

As per points f) and g), NIHO provided the space for professional opinion of clinical experts, as well as the space for the opinion of patients' organisations in all assessments.

The fulfilment of the KPIs for 2023 will be reviewed by the Supervisory Board of NIHO in 2024, and depending on the result thereof, the contribution to the functioning of NIHO will be decreased or maintained.

## 8. ANALYSIS OF DEVELOPMENT OF THE INSTITUTE

NIHO was established as at 1 January 2022, therefore the year 2022 was the first starting year. During that year, it was necessary to build up NIHO in all fields: personnel, professional or material and technical.

Throughout the year, NIHO team increased from 5 to 18 full-time employees. In addition, as at December 2022, contracts with further 5 employees were signed, therefore the professional staffing capacities are almost full for the year 2023. In the professional field, thanks to finding a high number of highly professional employees and international cooperation, NIHO managed to put itself onto the map of well-developed HTA institutions, as well as to generate significant savings to the PHI (40-times return on investment into NIHO's activity for 2022). In the material and technical field, NIHO met all obligations of a public institution, including the furnishing of premises and technical equipment of an analytical institution, while maintaining highly-efficient handling with the financial contribution for NIHO's activity from the health insurance companies.

Thus, in all fields, NIHO managed to create excellent preconditions essential for further fulfilment of its primary task, which is to assess technologies (mainly the medicinal products) applying for categorisation in the Slovak Republic in a professional manner.

### OPINION OF THE SUPERVISORY BOARD

The Supervisory Board has reviewed the management and activities of the Institute and has no objections thereto.



**MA. Michal Staňák, Dr.phil, AKC**  
Managing Director/CEO



ANNEXES:

**Annex No. 1: Approved financial statements as at 31 December 2022**