

U P D A T E

Central and Eastern European countries Q4 2025

Gergely Meszaros
ERN-Lung
2025/12/15

Challenges of the patient organizations

Funding

Critics on independence and reliance

Stability

Professionalism

„Outsourcing” of patient organizations’ tasks

„Delivering” the tasks of the Healthcare system



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Opportunities

Health-technology assessment (HTA)

Research*

Collaboration with stakeholders

Participation in the scientific work

Advocacy



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*<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075437/>

Who we are?

European Reference Networks

Working for patients with rare, low-prevalence and complex diseases
Share. Care. Cure.

Knowledge travels,
not the patients!

PATIENTS → **NATIONAL HEALTH-CARE PROVIDERS** → **SPECIFIC ERN**

CLINICAL GUIDELINES
RESEARCH & INNOVATION KNOWLEDGE
GENERATING & SHARING EVIDENCE
TREATMENT
ADVICE
TRAINING & E-LEARNING

CPMS V2.0, (Clinical Patient Management System)
EXABO (EXpert Advisory BOard)

Tool

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Patient Board

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What we do?

UDP
Find the Missing Piece

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UnDiagnosed Patients Working Group

Go East
ERN-LUNG

BREATHeREGISTRY

Patient Journey Sarcoidosis

- 1. First symptoms**
 - As multi-system disease possibly affecting any organ:
 - The 10 symptoms, right lower
 - Fatigue, memory issues
 - reddish skin, nodules, rash, rashes
 - shortness of breath (dyspnoea)
 - heart pain, palpitations
 - swollen lymph nodes, glands, joints
 - dry mouth (xerostomia), dry eyes (xerophthalmia)
 - neuropathic (painful) numbness (hands and/or feet)
 - blurred vision, vertigo, tinnitus
 - labral aches
- 2. Diagnosis**
 - Diagnosis needs to be quick, timely and well-managed: time from first symptoms, to pathological signs, to confirmed diagnosis.
 - Unexplained organ problems: prompting the patient to be seen by many doctors (not 'primary' diagnosis).
 - Commonly misdiagnosed: of treatments do not do (mis)diagnosis and/or change (mis)diagnosis long term and/or months.
 - Necessary biopsies are not always taken from sites to reach tissue.
 - Even severe symptoms may be intermittent and be missed by tests.
- 3. Treatment**
 - Patients from established, continuing or progressing disease:
 - Continuous diagnostic support is needed because of changing presentations and organ involvement and other opening, dissemination.
 - Systemic affliction requires holistic care with self-leading (non-leading) doctor.
 - Holistic care with a defined leading coordinating doctor.
 - The individual prognosis is unknown, and the coordinating doctor will therefore monitor and ask the patient and take symptoms seriously.
- 4. Follow-Up Care**
 - Because of the lack of prognostic parameters, the risk of disease and unexplained progression remains unclear.
 - For many patients, care is more a continuous diagnosis and treatment management task. Longer lasting disease often results in negative social and economic burden.
 - The doctor might see an acute or chronic infection that worsens (this has first patient might be challenging).

Need: Support for persistent symptoms, frequent misdiagnosis, Psychological, economic.

Identify: Recognition of symptoms of an unusual condition and prompt transfer to a specialist centre with a multidisciplinary diagnostic centre with a moderate number of cases avoiding expertise.

Identify: Defined pathway of care from mapping the affected organs to coordinated treatment including psychological and quality of life factors.

Identify: Holistic care with a defined leading coordinating doctor.

Identify: The individual prognosis is unknown, and the coordinating doctor will therefore monitor and ask the patient and take symptoms seriously.

Need: Clinician for single-offering patients to be seen in a specialist centre for treatment or for a second opinion.

Identify: In transition: the patient's GP knows the specialist doctor and transfer to the patient to the specialist (transfer to upper patient's request).

Identify: Specific coordinated diagnostic pathways to improve health competencies and reduce burden on open needs.

Go East - how it started and where we are...



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„... no single MS {Member State} in isolation will be able to provide access to the best possible healthcare in all areas of highly specialized health care for the residents of their country concerned by rare diseases”^o



ERN-Lung in Eastern European countries*

	AATD	CF	CLAD	ILD	MSTO	nCF-BE	ORLD	PCD	PH	Sarcoidosis
Bulgaria										
Croatia**										
Czech Republic										
Cyprus										
Estonia										
Greece										
Hungary										
Latvia										
Lithuania										
Poland										
Romania										
Slovakia										
Slovenia										

* including full members, affiliated partners, supporting partners & members

** TBC

- 6 applications received and approved*
- Hungary (Sarco, PH),
- Greece (2 PH),
- Slovenia (PH) and
- Poland (Sarco)



^oHéon-Klin, V. European Reference networks for rare diseases: what is the conceptual framework?. *Orphanet J Rare Dis* 12, 137 (2017). <https://doi.org/10.1186/s13023-017-0676-3>

ERN-Lung Academy



Position statement | [Open access](#) | Published: 19 December 2022

Rare disease education in Europe and beyond: time to act

[Birute Tumiene](#), [Harm Peters](#), [Bela Melegh](#), [Borut Peterlin](#), [Algirdas Utkus](#), [Natalija Fatkulina](#), [György Pfliegler](#), [Holm Graessner](#), [Sanja Hermanns](#), [Maurizio Scarpa](#), [Jean-Yves Blay](#), [Sharon Ashton](#), [Lucy McKay](#) & [Gareth Baynam](#)

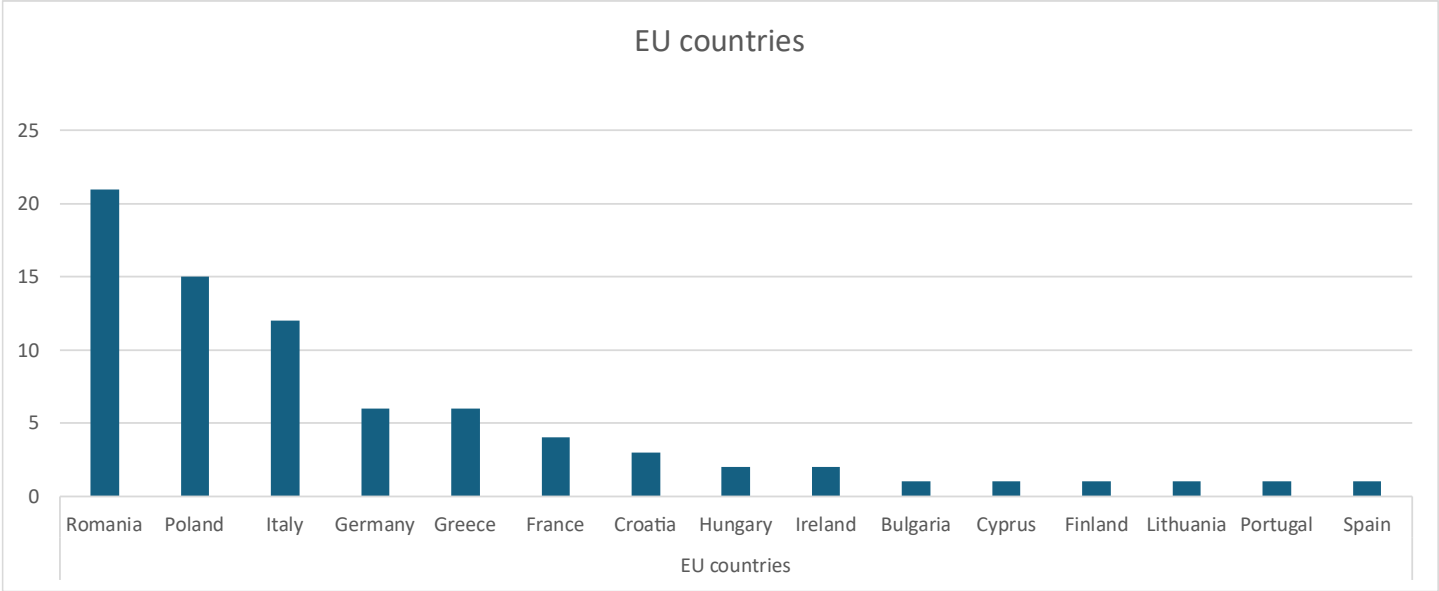
Orphanet Journal of Rare Diseases 17, Article number: 441 (2022) | [Cite this article](#)

6576 Accesses | 42 Citations | 3 Altmetric | [Metrics](#)



Level of rare disease knowledge and awareness among the current and future healthcare workforce is insufficient.

Data from 2025



- 1. Webinar (online) content
- 2. Practical (on-site) stay
- 3. Exam to be introduced

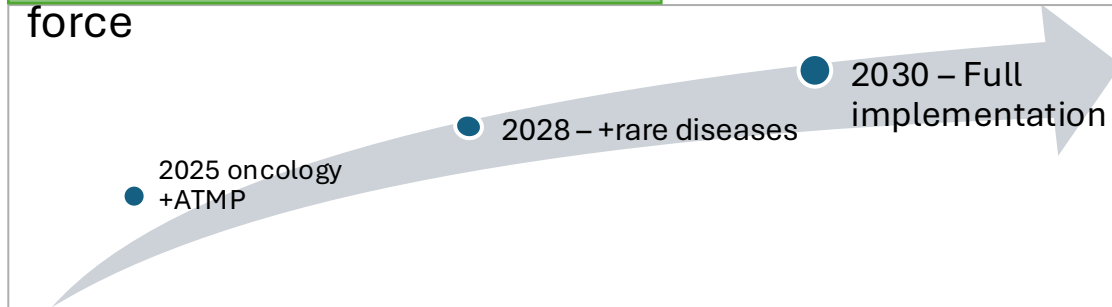
HTA (Health-technology assessment)



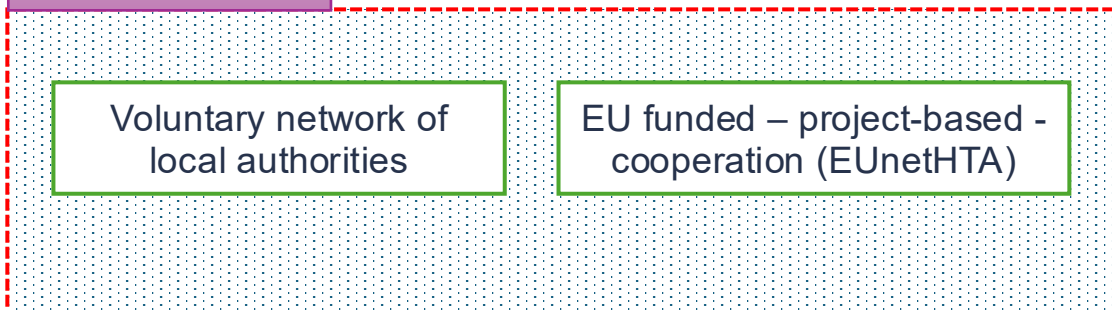
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HTAR (EU) 2021/2282 regulation

Step-by-step coming into force



Terminates



Establishes

Centralised EU-level assessment

Member states' responsibility:
definition of the populations, comperators and results (PICO)
Price/reimbursement decisions

Role of patients/patient advocates

Therapies in CEE region



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Table 2. Prevalence and incidence of pulmonary arterial hypertension and access to specific therapies in Central and Eastern European Countries

	Croatia	Czech Republic [36, Reply registry]	Latvia [37-39]	Lithuania	Poland [40]	Romania	Slovakia	Slovenia
No of patients with PAH/million adults	41.2 ^a	49.6 ^a	45.7 ^a	55.8 ^a	30.8 ^a	50 ^b	43 ^b	35 ^b
New diagnosis of PAH per year/million adults	5–6 ^b	8.5 ^a	9.0–12.04 ^a	7–8 ^b	5.2 ^a	4–5 ^b	5.4 ^b	5 ^b
National PAH registry [Yes/No]	No	Yes	Yes	Yes	Yes	No	No	No
Reimbursed therapies								
Bosentan po [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Macitentan po [Yes/No]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Ambrisentan po [Yes/No]	No	Yes	Yes	Yes	No	No	Yes	Yes
Sildenafil po [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tadalafil po [Yes/No]	Yes	Yes	Yes	No	No	No	Yes	No
Riociguat po [Yes/No]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Treprostinil sc/iv [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Treprostinil inh [Yes/No]	No	No	No	No	No	No	No	No
Treprostinil po [Yes/No]	No	No	No	No	No	No	No	No
Epoprostenol iv [Yes/No]	No	Yes	No	No	Yes	No	Yes	Yes
Selexipag [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Iloprost iv [Yes/No]	No	No	No	No	No	No	No	Yes
Iloprost inh [Yes/No]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Sotatercept sc [Yes/No]	Yes	Yes ^c	No	No	No	No	No	Yes ^c
Double oral combination ERA + PDE5i [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Triple combination ERA + PDE5i + Treprostinil sc/iv or Epoprostenol iv [Yes/No]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Quadruple combination ERA + PDE5i + Treprostinil sc/iv or Epoprostenol iv [Yes/No] + sotatercept	Yes	Yes ^c	No	No	No	No	No	No

The availability of oral treatment is wide, and all countries declare access to subcutaneous or intravenous treprostinil; however, epoprostenol and sotatercept are not available in most countries.

Emerging therapies and new directions in the treatment of pulmonary arterial hypertension Kopec et al. DOI: [10.33963/v.phj.104053](https://doi.org/10.33963/v.phj.104053)

^aBased on registry data. ^bBased on estimation. ^cEarly access program only

Abbreviations: inh, inhalation; iv, intravenous; PAH, pulmonary arterial hypertension; po, per os; sc, subcutaneous; other — see Table 1

Reimbursement of Winrevair (sotatercept)



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Fully approved: Spain,
Switzerland, Germany,
Greece, Slovenia, Czech
Republic and Croatia

Ongoing procedures in
many countries



Recent news

expanded indication to
IV based on the Phase 3
ZENITH study
(2025/12/12)

As of 2025/12/12

COUNTRY SPECIFIC UPDATES



Country-specific news*

Bulgaria



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Late-Stage Diagnosis

Over 90% of PAH patients were diagnosed at WHO Functional Class III, indicating late-stage disease.

Monotherapy Dominance

Most patients relied on monotherapy, with only 18.5% starting dual therapy and none on triple therapy.

Follow-Up Challenges

31% of patients were lost to follow-up, highlighting systemic gaps in continuity of care.

Advocacy and Future Actions

Calls for national PAH registry, improved screening, and patient engagement to enhance outcomes.

Czech Republic



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Updated treatment guidelines for PAH

Cor et Vasa published an expert consensus (2025) from the Czech Society of Cardiology, revising therapeutic algorithms for PAH. The update emphasizes initial combination therapy for patients without additional cardiorespiratory issues, and monotherapy with comorbidities, while highlighting the need for earlier diagnosis and more effective treatments. [e-coretvasa.cz]

Socioeconomic burden study

Presented at the ERS Congress (2025), a cross-sectional study involving 80 PAH patients and 19 caregivers assessed quality of life, work disability, and financial impacts. It found severely reduced work productivity (~30.5%), high disability pension rates, and significant caregiver burdens, comparable to those seen in advanced cancer care. [ispor.org], [publicatio..ersnet.org]



Hungary



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Tüdőér Egylet PH
November 2. · 🌐

Október 17-19 között rendezte meg a Magyar Szervátültetettek Szövetsége a Szervátültetettek Országos Találkozóját, azaz a Trapi-Napokat. Amikor a PH gyógyszeres keze... [Továbbiak](#)

Tüdőér Egylet PH
Október 27. · 🌐

Szerencsére szép őszi napra virradtunk október 25-én. PH betegek és hozzátartozóik egy csoportja, kicsik és nagyok együtt vágta neki egy túrának a festői szépségű Börz... [Továbbiak](#)



Poland



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National reimbursement of sotatercept for PAH

In June 2025, Poland's health technology agency (AOTMiT) approved **sotatercept** (Winrevair) for reimbursement in pulmonary arterial hypertension (PAH), adding it to the national treatment program. The decision was supported by trial data—most notably the ZENITH study—highlighting the drug's robust efficacy in advanced-stage PAH (WHO Class III and IV). Input from patient groups influenced the decision, emphasizing sotatercept's potential to enhance quality of life for PAH patients. [\[marketacce...stoday.com\]](#)

Expert consensus on emerging therapies

A multidisciplinary article in the *Polish Heart Journal* reviewed recent advances in PAH treatment since the 2022 ESC/ERS guidelines. The study involved experts from Poland, Latvia, Lithuania, Slovakia, Romania, Croatia, Slovenia, and the Czech Republic, underscoring an evolving therapeutic landscape across the CEE. [\[journals.v...amedica.pl\]](#)

Real-world patient data and COVID-19 impacts

A Polish registry-based study (June–September 2024) analyzed outcomes in PAH and CTEPH patients during COVID-19 (2020–2022). It examined infection rates, hospitalizations, mortality, vaccination response, and long-term prognosis. Findings are pending full publication. [\[mp.pl\]](#)



Romania



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#goodPHnews from Romania

Progress and advocacy for pulmonary hypertension patients.

A recent working-group meeting, held as part of the AER project (Efficient Access to Health System Resources for Patients), focused on analyzing the challenges faced by patients with pulmonary hypertension in Romania, particularly access to diagnosis, treatment, and financing.

Asociația Pacienților Hipertensivi Pulmonari, together with COPAC (Coalition of Organizations of Patients with Chronic Disorders) and Point PA&PR, led discussions on ensuring uninterrupted treatment, improving patient monitoring, and including psychological support and transport services in reimbursed healthcare packages. A key priority was the creation of a centralized registry of PH patients, planned for implementation by summer 2026, as well as the establishment of a national center of surgical expertise to provide specialized interventions.

Representatives of CNAS (Casa Națională de Asigurări de Sănătate, the Romanian National Health Insurance House) expressed support for these initiatives, highlighting the importance of a strategic, patient-centered approach to rare diseases like pulmonary arterial hypertension (PAH).

Asociația Pacienților Hipertensivi Pulmonari continues to play a vital role in advocating for equitable access to care and turning systemic challenges into concrete solutions for the PH community in Romania.

#PHAEurope #Romania #pulmonaryhypertension #pulmonaryhypertension #PAH #CTEPH #awareness #patientempowerment #patientassociation #raredisease #respiratorycare

Asociația pacienților cu hipertensiune pulmonară din România



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Program preliminar

ȘCOALA PNEUMOClinics TM 2025

„Respirând Excelență – Expertiza și viziunea care pot redefini abordarea patologiei pulmonare”

Timișoara, 16 – 18 octombrie 2025

Joi 16 octombrie 2025

09.00-11.20 Sesiune plenară I – Aula Magna UMFVBT (transmitere on-line)

Moderatori:

Conf.univ. Dr. Monica MARC, UMF „Victor Babeș” Timișoara

Șef Lucr. Dr. Camelia PESCARU, UMF „Victor Babeș” Timișoara

Simpozion – Stilul de viață și sănătatea respiratorie: prevenție, protecție, performanță
09.00-09.15 Terapia farmacologică pentru pacientul fumător – Prof.univ. Dr. Florin MIHĂLȚAN, Asist.univ. Dr. Ancuța Alina CONSTANTIN, UMF „Carol Davila” București
09.15-09.30 Prevenția precoce: drumul către un plămân sănătos începe din copilărie – Prof.univ. Dr. Ioana CIUCĂ, Clinica Universitară Pediatrie II, UMF „Victor Babeș” Timișoara
09.30-09.45 Rolul alimentației în cancerul pulmonar; de la risc la prevenție – Prof.univ. Dr. Elena DANTES, Facultatea de Medicină, Universitatea „Ovidius” Constanța
09.45-10.00 Microbiomul pulmonar și impactul probioticelor asupra acestuia – Șef Lucr. Dr. Emanuela VAȘTAG, Clinica Universitară Pneumologie, UMF „Victor Babeș” Timișoara

10.00-10.20 TBD – Prof.univ. Dr. Bogdan TIMAR, UMF „Victor Babeș” Timișoara (1 prezentare pentru NovoNordisk)

Romanian–European Dialogue on Pulmonary Hypertension 2025: Partnership between Experts and Patients

Nov 21–22, 2025 · UMFST Târgu Mureș

A modern edition focusing on risk stratification and novel biomarkers.

Slovakia

www.herba.sk

CLINICAL STUDY

EVIDENCE OF AN EXCELLENT INTERNATIONAL COOPERATION IN THE MANAGEMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION

Dôkaz výbornej medzinárodnej spolupráce v liečbe chronickej tromboembolickej pľúcnej hypertenzie

Tereza HLAVATÁ¹, Adriana REPTOVÁ¹, Pavel JANSÁ², Samuel HELLER², Filip KLAUČO¹, Martha Irene LANG³, Maria SZÁNTOVÁ⁴, Iveta ŠIMKOVÁ¹

¹Expert CTEPH Center, Department of Cardiology and Angiology, Slovak Medical University, National Institute for Cardiovascular Diseases, Bratislava, Slovakia, Head of the Department prof. I. Šimková, MD, PhD.

²PH Center, 2nd Department of Internal Medicine - Department of Cardiovascular Medicine, Charles University, General University Hospital, Prague, Czech Republic, Head of the Department prof. A. Linhart MD, DrSc.

³Department of Internal Medicine II, Cardiology, Medical University of Vienna, Austria, Head of the Department: Prof. Ch. Hengstenberg, MD, PhD.

⁴3rd Department of Internal Medicine, Comenius University and University Hospital Bratislava, Bratislava, Slovakia, Head of the Department Assoc. prof. M. Szántová, MD, PhD.

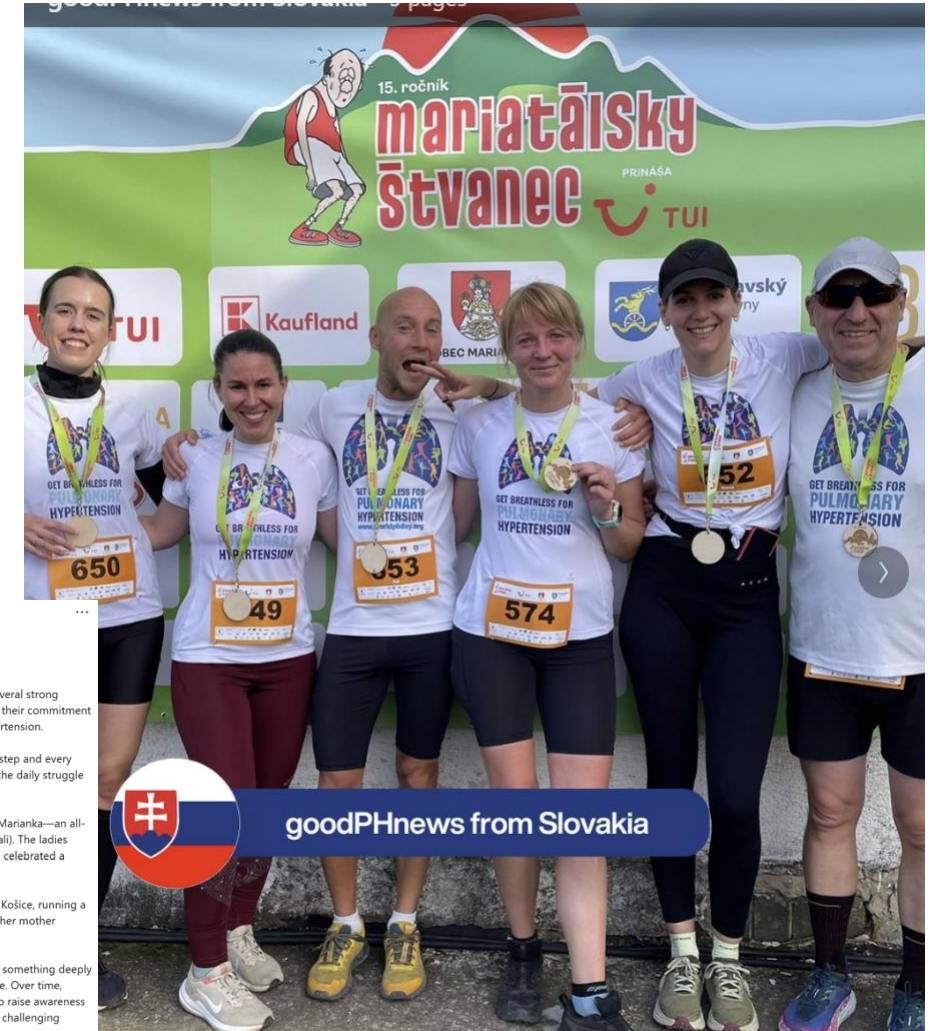


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#goodPHnews from Slovakia sk

PHA Slovakia has recently (in September and October) carried out several strong advocacy and awareness initiatives, leaving everyone breathless with their commitment and solidarity with all those facing the challenges of pulmonary hypertension.

Among these were sports events, marathons and races, where every step and every breath becomes a powerful reminder to those with healthy lungs of the daily struggle faced by people living with PH.

Two teams proudly represented the association at a beautiful run in Marianka—an all-female team (Zuzka, Viki, Hanka) and a mixed team (Zuzka, Danko, Pali). The ladies missed the podium by just a hair, finishing 4th, while the mixed team celebrated a wonderful 3rd place.

Meanwhile, Monika took part in the International Peace Marathon in Košice, running a half marathon to raise awareness for PAH patients and especially for her mother Helena, who is also bravely fighting this disease.

Every act of advocacy and awareness in the PH community begins as something deeply personal and emotional, rooted in love, courage, and lived experience. Over time, these personal stories grow into powerful collective action, helping to raise awareness not only for our loved ones but for everyone living with this rare and challenging condition.

PHAEUROPE warmly congratulates PHA Slovakia on these heartfelt initiatives and their unwavering dedication to awareness, advocacy, and hope for the entire PH community.



Thank you for your attention!