





# TOWARDS A EUROPEAN MIGRAINE ACTION PLAN: KEY POLICY RECOMMENDATIONS

Sponsored by Pfizer. Brussels, 2024

Endorsed by the European Migraine and Headache Alliance (EMHA), the European Brain Council (EBC), the European Federation of Neurological Associations (EFNA), the European Patients Forum (EPF), the Migraine Trust, Cittadinanzattiva-Active Citizenship Network, the European Institute of Women's Health (EIWH), Hoofdstuk and GAMIAN Europe.

# **OVERVIEW**

This document sets out the ambitious vision of leading European Union (EU) migraine policy stakeholders to address the huge burden of migraine on European citizens and society – an extremely common neurological disorder in the EU impacting 14.7% of adults<sup>1</sup>. It outlines key policy proposals within a **dedicated EU Migraine Action Plan** to improve the lives of people living with migraine and protect the sustainability of Europe's healthcare systems.

The EU Migraine Action Plan is the result of a policy workshop, sponsored by Pfizer, which brought together leaders from the European Migraine and Headache Alliance (EMHA), the European Brain Council (EBC), the European Federation of Neurological Associations (EFNA), the European Patients Forum (EPF), the Migraine Trust, Active Citizenship Network (ACN), the European Institute of Women's Health (EIWH) Hoofdstuk and GAMIAN Europe.

# THE BURDEN OF MIGRAINE IN EUROPE

- Migraine poses a significant public health challenge in the European Union (EU), impacting approximately 41 million individuals<sup>2</sup>. This neurological disorder, more prevalent among younger populations and women, often manifests as chronic migraines, with 83% of sufferers enduring its effects for over a decade<sup>3</sup>. The associated economic burden is substantial, with indirect costs, such as reduced productivity and absenteeism, contributing to an annual expense of €111 billion in the EU<sup>4</sup>.
- Migraine burdens all healthcare systems, regardless of their level of access to treatment. Migraine-related productivity losses lead to foregone employment earnings directly affecting individuals. The government is affected due to reduced tax contributions, the public sector productivity loss and the state of disease-induced dependency which increases social transfers (i.e.: unemployment or disability benefits).
- Beyond its economic impact, migraine is linked to various comorbidities which can further exacerbate pressure on healthcare systems. For example, migraines are strongly associated with depression and anxiety, with individuals affected by migraine being 2 to 10 times more likely to experience a mood disorder compared to the general population<sup>5</sup>. Despite migraine's significant burden on Europe, there is a perception that migraine remains both misunderstood and deprioritized on the healthcare agenda.

# THE EU MIGRAINE ACTION PLAN RECOMMENDS POLICY ACTION SHOULD FOCUS ON:

- **1)** Approaching migraine holistically from a policy perspective.
- 2) Ensuring relevant funding for migraine from policy bodies as a neurobiological chronic disease to improve migraine patient outcomes across the EU.
- **3) Increasing understanding** of migraine as a chronic condition.
- 4) Integrating the voice of migraine patient community into healthcare policy decision-making.
- 5) Ensuring migraine is adequately addressed through unmet medical need (UMN) in the revision of the EU's Pharmaceutical Legislation.



# WE CALL ON EUROPEAN UNION POLITICAL LEADERS TO:

# **1.** APPROACH MIGRAINE HOLISTICALLY FROM A POLICY PERSPECTIVE

**BEBC** 

EMHA European Migraine & Headche Alliance

## **EU LEVEL**

- Advocate for the explicit integration of the rights and needs of individuals with migraine into the European Social Pillar, recognizing impact on employment, education, and social protection. Policymakers should actively collaborate with relevant stakeholders to ensure the development of comprehensive policy frameworks and incentives supporting employment, work flexibility, return-to-work, or retention-at-work of individuals with migraine.
- Endorse a holistic approach to migraine management that seamlessly integrates support into individuals' lives, fostering inclusivity. Prioritize prevention to reduce the overall burden on both individuals and the community, aligning with proactive and integrated healthcare policies.

#### MEMBER STATE LEVEL

- Advocate for the creation of holistic national migraine plans and clear patient pathways (and/or integrate them into national Brain Plans when existing). Member States must be proactive and understand the cost of inaction when it comes to migraine diagnosis and treatment. There is a need to provide a personalized approach to migraine patients, from employment incentives to raising awareness and tackling stigma. Sex/gender disparity for migraine must also be taken into consideration.
  - Spain has already committed to publish their national migraine plan soon and other Member States should follow suit.
  - The Italian senate recently laid a historic milestone when it approved legislation recognizing chronic primary headache, including migraine, as a disease with a social impact.

# 2. ENSURE RELEVANT FUNDING FOR MIGRAINE FROM POLICY BODIES AS A NEUROBIOLOGICAL CHRONIC DISEASE TO IMPROVE MIGRAINE PATIENT OUTCOMES ACROSS THE EU

## **EU LEVEL**

- Specifically, call upon the European Commission, the Directorate-General for Health and Food Safety (DG SANTE), Directorate-General for Budget, the Economic and Financial Affairs Council (DG ECOFIN), Directorate-General for Research and Innovation (DG RTD), and the European Health and Digital Executive Agency (HaDEA) to prioritize the allocation of resources to improve migraine (emphasis on chronic disease) patient outcomes. This includes leveraging funding instruments such as Horizon Europe and the EU4Health Program.
- Policymakers should actively collaborate with relevant stakeholders, including the scientific community and patient advocacy groups, to ensure a strategic and impactful allocation of funds.

## MEMBER STATE LEVEL

- Call upon national health authorities, budgetary bodies, and research agencies to prioritize the allocation of resources to improve chronic disease patient outcomes. This includes leveraging national funding mechanisms and actively seeking additional support from the Recovery and Resilience Facility (NextGenerationEU funds).
- Encourage local health bodies to review the healthcare needs of their communities living with migraine and develop targeted plans based on these insights. This will ensure precise and effective support for individuals with consideration of specific demographics.

# **3. INCREASE UNDERSTANDING OF MIGRAINE AS A CHRONIC CONDITION**

#### **EU LEVEL**

 Call upon the European Commission and more specifically DG SANTE to update the NCD Initiative document and include a specific section on migraine which is the second largest contributor of neurological Disability-Adjusted Life Years (DALYs) in the EU. Ideally, this would include specific guidance for Member States regarding on how to improve migraine patient outcomes and increase healthcare system sustainability.

#### **MEMBER STATE LEVEL**

- Call upon national health ministries and regional authorities to formally recognize migraine as a chronic disease with a significant economic and social impact on patients and healthcare systems.
- Collaborate with medical associations, local healthcare providers, and institutions to foster better patient care and support and to consider sex and gender differences in migraine prevalence progression and treatment needs. Additionally, integrate migraine as a chronic disease into broader public health strategies at both national and EU levels. Actively include migraine in health promotion campaigns, disease prevention initiatives, and overall health strategy planning.

# 4. INTEGRATE THE VOICE OF MIGRAINE PATIENT COMMUNITY INTO HEALTHCARE POLICY DECISION-MAKING

## **EU LEVEL**

- Ensure the European Commission enforces EU-wide HTA aspirations regarding patient involvement and widens their role in HTA processes, where individuals with migraine and patient advocacy groups actively contribute to policy development. Policymakers should actively seek diverse representation and perspectives from those directly affected by migraine, creating policies aligned with patient needs and experiences.
- Promote accessible information and participation opportunities, ensuring clear communication of policy initiatives and creating inclusive platforms, such as online forums and public hearings, to gather input from a diverse range of voices within the migraine patient community.

#### MEMBER STATE LEVEL

• Call upon national health ministries and national HTA

bodies to comply with EU level recommendations and actively include patients with lived experience as part of their decision-making process.

 Currently, out of the 23 European countries that have an HTA system for the assessment of pharmaceuticals, only 9 indicate involving patients in the HTA at the step of advice and decision-making.

# 5. ENSURE MIGRAINE IS ADEQUATELY ADDRESSED THROUGH UNMET MEDICAL NEED (UMN) IN THE PHARMACEUTICAL LEGISLATION

## **EU LEVEL**

• Request MEPs to include migraine within the ongoing EU general pharmaceutical legislation discussions. The current criteria for UMN focus (life-threatening disease, or seriously debilitating disease with remaining high morbidity or mortality), may overlook conditions like migraine, which have a substantial societal and economic impact, including the risk of chronification through overuse of medication. Migraine affects 41 million adults in Europe, contributing to an annual cost of EUR 111 billion. By expanding the UMN criteria to encompass conditions such as migraine, we can ensure a more comprehensive approach to healthcare policy, addressing the needs of a significant population. It may also facilitate the creation of a preventive plan to curb medication overuse and avoid the chronification of migraine, enhancing the overall effectiveness of healthcare strategies.

#### MEMBER STATE LEVEL

 Call upon Member State representatives (Permanent Representation Health Attachés and ministry staff) active in the EU general pharmaceutical legislation to revise the current definition of UMN and ensure conditions like migraine which severely impact quality of life and present huge economic costs are not ignored and improve customers' product performance.

# REFERENCES

 Bloudek, L. M., Stokes, M., Buse, D. C., Wilcox, T. K., Lipton, R. B., Goadsby, P. J., Varon, S. F., Blumenfeld, A. M., Katsarava, Z., Pascual, J., Lanteri-Minet, M., Cortelli, P., & Martelletti, P. (2012). Cost of healthcare for patients with migraine in five European countries: results from the International Burden of Migraine Study (IBMS). The journal of headache and pain, 13(5), 361–378. https://doi.org/10.1007/s10194-012-0460-7

**2.** RETHINKING Migraine in times of COVID-19. European Brain Council. 2022. https://www.braincouncil.eu/wp-content/uploads/2022/06/RETHINKING-Migraine\_report\_V5\_17062022.pdf

**3.** Access to care" Project: Final Assessment. European Migraine & Headache Alliance. 2021. https://www.emhalliance.org/wp-content/uploads/EMHA-Julio-2021-1.pdf

**4.** Linde, M., Gustavsson, A., Stovner, L. J., Steiner, T. J., Barré, J., Katsarava, Z., Lainez, J. M., Lampl, C., Lantéri-Minet, M., Rastenyte, D., Ruiz de la Torre, E., Tassorelli, C., & Andrée, C. (2012). The cost of headache disorders in Europe: the Eurolight project. European journal of neurology, 19(5), 703–711. https://doi.org/10.1111/j.1468-1331.2011.03612.x

**5**. Duan, S., Ren, Z., Xia, H., Wang, Z., Zheng, T., Li, G., Liu, L., & Liu, Z. (2023). Associations between anxiety, depression with migraine, and migraine-related burdens. Frontiers in neurology, 14, 1090878. https://doi.org/10.3389/fneur.2023.1090878