EMHA Position Paper on the EU Pharmaceutical Package Revision

The ongoing trilogue negotiations on the EU Pharmaceutical Package represent the most significant reform of EU medicines law since 2004. At the heart of this revision lies the definition of *Unmet Medical Need (UMN)* — a concept that will guide future incentives, authorisation pathways, and equitable access to medicines across Europe.

For the 41 million Europeans living with migraine and headache disorders, this reform is not an abstract legal exercise. It will determine whether new, effective, and accessible treatments emerge in the coming decade. Migraine is one of the leading causes of disability worldwide — and the first among young women — yet current therapies remain insufficient, poorly tolerated, or unevenly available across Member States.

Recognising the **burden of neurological and chronic disorders** within the definition of UMN is essential to ensure that innovation incentives address patients' lived realities rather than narrow clinical endpoints.

A Balanced and Patient-Centred Approach to Defining UMN

EMHA welcomes the **European Parliament's patient-oriented definition** of Unmet Medical Need, which rightly reflects the multifaceted impact of disease, including functional disability, quality of life, and social participation. This approach anchors innovation policy in real-world patient outcomes rather than in purely clinical or technical parameters.

At the same time, EMHA recognises the value of the **Council's formulation**, which considers that UMN can be established when *any* of the listed criteria apply — an "alternative" rather than cumulative approach. This distinction is significant: while the Parliament requires that *all* criteria be met simultaneously, the Council's flexibility better reflects the diversity of patient experiences and the varying dimensions of need across disease areas.

EMHA therefore supports a **hybrid approach** — combining the Parliament's comprehensive, patient-centred vision with the Council's flexibility — to ensure that the final definition of UMN is both inclusive and operational, fostering innovation where it is most needed.

EMHA Recommendations

- **Adopt a broad and flexible definition** of Unmet Medical Needs that captures real-world disease impact — including functional impairment, quality-of-life loss, and social participation.
- **Allow alternative fulfilment of UMN criteria**, ensuring that conditions with significant burden in any of the defined dimensions are not excluded.
- **Integrate patient perspectives and Patient Experience Data** into the definition and evaluation of UMNs across legislative and EMA guidance frameworks.
- **Preserve strong incentives for innovation** in chronic and disabling conditions where existing treatments remain inadequate or poorly tolerated.
- **Ensure coherence between UMN criteria and access obligations**, avoiding disincentives that could deter research investment in brain health and neurological diseases.
- **Institutionalise patient involvement** in the design, assessment, and implementation of UMN-related policies and evaluation processes.

Key Concerns

- A **restrictive or purely clinical definition** of UMN could exclude conditions like migraine, where unmet needs persist despite available therapies.
- Applying criteria **cumulatively rather than alternatively** could narrow the definition excessively, overlooking significant areas of medical need.
- Overemphasis on **administrative simplicity** may weaken incentives needed to sustain research in chronic and disabling disorders.
- **Quality of life, disability, and access inequalities** risk being overlooked if UMN assessment remains detached from real patient outcomes.
- **Limited patient participation** in defining UMN would undermine the legitimacy and effectiveness of the new framework.

Conclusion

EMHA calls on EU institutions to adopt a **balanced, evidence-based, and patient-centred definition** of Unmet Medical Need — one that combines the inclusiveness of the Council's approach with the patient focus of the Parliament's proposal.

Such a definition would capture the full impact of conditions such as migraine and other chronic neurological disorders, while ensuring that Europe's pharmaceutical legislation remains a driver of meaningful innovation and equitable access.

Recognising migraine as a **serious, disabling, and still underserved condition** will help ensure that this historic reform delivers on its promise: fostering innovation that translates into tangible, equitable health improvements for all Europeans.