

EPF – Medicines for Europe Dialogue
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Improving patients experience through *Off-Patent Research*

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Empowering Patient Neurology Groups

MEP Interest Group on Brain, Mind and Pain

Aims to: Encourage research into and access to innovative treatments, promote prevention and self-management approaches, decrease stigma and work together to improve quality of life for people living with these disabling conditions.

- Support patient-led campaigns to educate, eradicate stigma and raise awareness of neurological and chronic pain disorders
- **Support research** into the development of innovative prevention and treatment options within a regulatory framework which facilitates equitable access to affordable therapies
- **Strengthen patient involvement** in this research, and in policy setting and decision-making
- Implement relevant European social legislation to ensure appropriate support for people living with neurological and chronic pain disorders



Our Book of Evidence: The Challenges

- Only 8% of CNS drug candidates succeed (compared to 15% in other disease areas)
- CNS drugs take longer to develop: late-stage clinical development takes one third longer than for other categories
- Diseases amongst most complex and least understood in medicine
- Research is hampered by issues such as the relative inaccessibility of brain tissue
- This means when drugs do come to market, they are often hugely expensive – limiting access and availability



Member of the
European Parliament
INTEREST GROUP ON
BRAIN, MIND AND PAIN

The Book of Evidence

However...

- Most treatments for neurological conditions are small molecules
- These are relatively simple to imitate, so competitor drugs, including generics, can be rapidly developed
- Few economic incentives for industry to invest in repurposing old treatments for new diseases, or to investigate new treatment combinations which combine both old and new drugs
- Such approaches likely to be particularly important in developing new treatments for brain disorders

It is in everyone's interest to find a balance between minimising treatment costs to patients (e.g. through generics) and continuing to incentivise innovative drug development and drug repurposing activities that will ultimately benefit patients.

So...

- We would like to see more off-patent research and development in the field of brain disorders, with active and meaningful patient involvement throughout.
- Particularly important for neurology where the most impactful symptoms and disease progress often cannot be directly measured: must be assessed using questionnaires or interviews with patients.
- These are fluctuating, chronic conditions with – in most cases – no cure, so PROMs are often more focussed on overall quality of life from a socio-economic perspective rather than isolated symptomatic improvements i.e. return to work.
- In off-patent R&D – where race to market is of less relevance – is there scope to better include what matters most to the patient?

Suggested topics for consideration today...

- Has anyone/any patient organisation had experience of participation in off-patent research? Was that experience positive or negative?
- For industry, what had previously worked well or not worked at all – in terms of patient involvement. Were there gaps in terms of knowledge/skills from either/both sides? How can we address this?
- Ideally, where and how should patients engage in the process? What does that pathway look like?
- How can patients and industry work together to set PROMs?
- How can industry and patient organisations work together to ensure these PROMs are also part of subsequent decision making in terms of reimbursement and access?
- Next steps?