

JOINT POSITION



European Parliament
Draft report on a pharmaceutical strategy for Europe
(2021/2013(INI))
Committee on the Environment, Public Health and Food Safety

Brussels, 6 October 2021

We welcome the work that the European Union (EU) is doing to develop a comprehensive Pharmaceutical Strategy for Europe as well as the Parliament's critical involvement in shaping it.

We note that one of the Strategy's central objectives is to foster innovation, including in areas of unmet medical need. **To that end, we call on the European Parliament to explicitly mention in the Strategy neurological disorders**, which present an area of huge unmet needs, because:

Neurological disorders are the leading cause of Disability Adjusted Life Years (DALYs – a combination of years lived with disability and lost due to premature death) and second leading cause of death worldwide.

In Europe, neurological disorders rank third for DALYs and mortality, respectively – where they affect at least 1 in 3 people and cost Europe societies €336 billion annually (see [The burden of neurological diseases in Europe: an analysis for the Global Burden of Disease Study 2017](#) and [Commission's: Deaths and disability-adjusted life years within the EU in 2017 from NCDs](#)).

Despite many recent breakthroughs in the brain science, neurological disorders remain at the very end of the preventable burden scales assessing the potential to reduce the disease burden of the most prevalent diseases. In fact, some predictions show that at a current pace, only 23% of the global disease burden for neurological conditions can be averted by 2040 by scaling up existing treatments (see Exhibit 3, page 170 of [McKinsey on Healthcare: 2020 Year in Review](#)).

This extraordinary burden of neurological disorders was recognized at the **UN High-Level meeting in 2018**. Here, **neurological and mental health disorders were added as the "5th NCD"**, complementing global efforts to combat cancer, cardiovascular disorders, diabetes and respiratory disease.

Thereafter, in 2020, **WHO adopted a resolution "Global actions on epilepsy and other neurological disorders"**. All the 27 EU member states co-sponsored the resolution and a corresponding 10-year Global Action Plan (GAP) is currently being developed by WHO.

Against this backdrop, the **EU4Health Programme now lists neurological disorders among the 6 major NCDs** that should be addressed in the EU as a priority.

It will be critical that the EU Pharmaceutical Strategy aligns with those developments.

Therefore, we call for the following changes to be made in the legislative proposal:

<p>Compromise Amendment 2 (on the investments in R&D on pharmaceuticals) Compromise amendment replacing Amendments: 152-169, 171-173, 177, 562</p> <p>Amendment 2 Motion for a resolution Paragraph 2</p>	
<p><i>2. Considers that investment in research has not been sufficient to meet the therapeutic needs of patients with rare diseases, paediatric cancers and neurodegenerative diseases or to deal with antimicrobial resistance (AMR);</i></p>	<p><i>2. Recalls that public and private investments should be oriented with the necessary regulatory and legislative measures to meet the therapeutic and diagnostic needs of patients, including rare and chronic diseases, rare adult cancers and paediatric cancers and neurological disorders including neurodegenerative diseases or to deal with antimicrobial resistance (AMR);</i></p>

<p>Compromise Amendment 4 Compromise amendment replacing Amendments: 134, 197 - 213, 216, 217-219, 221, 222, 224, 229, 232, 234, 249</p> <p>Amendment 4 Motion for a resolution Paragraph 4</p>	
<p>4. Calls on the Commission to incorporate new criteria into the system of incentives for research into and the development of new medicines for unmet therapeutic needs, prioritising projects promoted by the pharmaceutical industry combating rare diseases, paediatric cancers, neurodegenerative diseases and AMR, with the aim of finding more therapeutic options and meeting the needs of patients and health systems; calls on the Commission to promote the creation of an EU framework to guide and regularly evaluate the implementation of national plans to fight these diseases;</p>	<p>4. Calls on the Commission to assess, and revise where appropriate, the system of incentives to promote research into and the development of new medicines for unmet diagnostic and therapeutic needs, prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry combating cancers paediatric cancers especially to incentivise first-in-child development of paediatric anticancer medicines, rare diseases, neurological disorders including neurodegenerative and mental illnesses and AMR, with the aim of finding more therapeutic options and meeting the needs of patients and health systems;</p>

EXPLANATORY STATEMENT

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In order to increase research and development of medicines for unmet therapeutic needs, the rapporteur calls on the Commission to promote the creation of a European framework to guide the implementation of national plans and strategies to combat rare diseases, paediatric cancers, neurodegenerative diseases and antimicrobial resistance.

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Justification: Neurodegenerative diseases (Parkinson's, Alzheimer's, spinal muscular atrophy, etc.) are diseases in which certain neurons gradually die ("degenerate"); the causes are varied and so do the parts of the nervous system. **All neurodegenerative diseases are neurological diseases**, i.e. organic diseases of the nervous system. Some of the most common neurological disorders include stroke, Alzheimer's disease, migraine, Parkinson's disease, epilepsy and multiple sclerosis. In total, there are over 400 neurological disorders.

Thank you for considering implementing those changes.

With kind regards,

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