BRAIN DISORDERS: THE NEED FOR IMPROVED TREATMENT

European Parliament Interest Group on Mental Health, Well-being and Brain Disorders

Brussels, 2nd June 2015

Prof. David Nutt
Frédéric Destrebecq
Agenda

• The European Brain Council
  • Presentation
  • Achievements
  • Publications
  • Advocacy

• The CINP White Paper
  • Main issues
  • Proposed actions
  • Stakeholders’ response
Acting as the common platform for the «brain space»

- Uniting patient, scientific, medical and industry perspectives around a common vision

- From which brain space can speak with one voice

- Recognized by EU and other institutions as such
Bringing together patients, scientists, clinicians and industries since 2002

- Promoting brain research in Europe and improve the quality of life of those affected by brain diseases

- Supporting basic and clinical research in Neuroscience

- Fostering dialogue bw. Science & Society
EBC Board Members

- **EFNA** – European Federation of Neurological Associations
- **GAMIAN Europe** – Global Alliance for Mental Illness Advocacy Networks
- **EAN** – European Academy of Neurology
- **EANS** – European Association of Neurosurgical Societies
- **ECNP** – European College of Neuropsychopharmacology
- **EPA** – European Psychiatric Association
- **FENS** – Federation of European Neuroscience Societies
- Industry partners
EBC Associate & Observers

- **B4B** – Brains 4 Brain
- **Euro-CNS** – European Confederation of Neuropathological Societies
- **EUFAMI** – European Federation of Associations of Families of People with Mental Illness
- **ESO** – European Stroke Organisation
- **FEPS** – Federation of European Physiological Societies
- **ESN** – Federation of the European Societies of Neuropsychology
- **ILAE-CEA** – International League Against Epilepsy - EU
- **National Action Groups and Brain Councils**
EBC contributed to increased funding in Brain Research

- Mapping of cost & burden of major brain diseases
  Paper published in 2005 and 2010

- Consensus for Brain Research
  Paper published in 2006 and 2011
Early Publications

• The Burden of Brain Diseases in Europe
  Olesen J and Leonardi M. Eur J Neurol 2003, 10:471-7

• Cost of Brain Disorders in Europe

• Size and Burden of Mental Disorders in Europe

• Research Allocation for Brain Research in Europe

• Consensus Document on European Brain Research
  Olesen J, Baker MG et al. J Neurol Neurosurg Psychiatry 2006, 77
2010: Total cost of Brain Disorders in Europe amounted to €798 billion

- Cost Document released in 2011
- Continuation of first study (2004): + €386 billion
- More than 1/3 of Europe’s population affected

*European Neuropsychopharmacology 2011; 21: 715-780*
Cost of Brain Disorders in Europe – 2010

Indirect costs 40%
Direct healthcare costs 37%
Direct non-medical costs 23%

Neurological Disorders
Indirect costs 26%
Direct healthcare costs 34%
Direct non-medical costs 40%

Mental Disorders
Indirect costs 48%
Direct healthcare costs 39%
Direct non-medical costs 13%

TOTAL
European Neuropsychopharmacology 2011; 21: 715-780
Cost of Brain Disorders in Europe – 2010

European Neuropsychopharmacology 2011; 21: 715-780
Consensus Document – 2011

• Collection of 45 research themes updated from 2006
• Used for selection of topics in first calls of FP7
• Revision reflecting changes in research priorities and advances
• Multi-authored, multi-national:
  • 200 European scientists and patients organizations
  • proposals for future research programmes
  • needs and achievements of research in Europe

*European Journal of Neuroscience, Vol. 33, pp. 768–818, 2011*
EBC advocates for better funding of brain research

<table>
<thead>
<tr>
<th></th>
<th>FP5 (pre EBC)</th>
<th>Total in FP6</th>
<th>FP7 2007 - 2013</th>
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</thead>
<tbody>
<tr>
<td><strong>Brain</strong></td>
<td>115m</td>
<td>431m</td>
<td>3b *</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td>235m</td>
<td>914m</td>
<td>2.2b</td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td>54m</td>
<td>232m</td>
<td>737m</td>
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* Updated: June 2015
National Brain Councils & Action Groups
2011-2015

• 30 NBCs and NAGs developed
• Pushing for research at local level
• Providing vital grass roots knowledge to the EBC
• Enabling progress at country level
• First Session of NBCs Academy: 17th June 2015
Awareness Raising & Advocacy

1st European Day of the Brain.
Ageing, Stroke, and Alzheimer's Disease
- Finding Innovative Solutions

Open your mind!
European Month of the Brain
May 2013  #brainmonth

Year of the Brain in Europe
YotB served as pan-European campaign to change the way we perceive our brain

• A programme to raise awareness, educate and challenge current perceptions
  • 200 organisations have pledged their support

• Main themes:
  ▪ Education
  ▪ Awareness
  ▪ Research
  ▪ Ethics
  ▪ Extensive brain ambassadors campaign
INNOVATIVE PARTNERSHIPS TO ACCELERATE CNS DRUG DISCOVERY FOR IMPROVED PATIENT CARE

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CNS disorders are the understated health challenge of the 21st Century

- One third of people will develop brain disorders
- Revenues from CNS drugs are predicted to decrease, prompting investors to withdraw their support
- CNS disease research area is seen as the most unpredictable and costly, with a high rate of failure

- Hence, dilemma for investors in an area with high unmet need and potential for development, but with high risks
We need to revisit the Value Chain for brain disorders

• The societal impact of brain disorders is growing
  Stigma - Demographic changes - Economic Impact

• Non accessibility of treatment
  High cost of treatment - Long waiting time
  – reimbursement & approval

• Brain research lacks input and innovation
  Brain research is underfunded – Industry withdraws from the area
Topic #1
Connecting Science & Regulation
A better understanding of brain function is needed

Issues with:
- Higher complexity in CNS
- Few biomarkers & little molecular definition of illnesses
- No clearly defined endpoints
- Poorer understanding than for other conditions
Proposed solution through

- Collaborative & open approach in drug development
- Improved dialogue re-running of clinical trials
- Sustained communication – unhindered by robust conflict of interest policies
- Refined regulatory processes against scientific advances
- Attracting investment in basic and clinical research
Topic #2
Benefit-Risk – Effective research & Implementation into clinical practice
Clinical trials & real-life practice are disconnected

- Narrow criteria for recruitment
- Oversight on co-medication, adherence or adverse effects

• How to ensure real-life effectiveness?
• How to develop new valid clinical trials designs?
Innovative clinical trials w. clear & relevant endpoints should be developed

- Faster access to market
- Lower cost
- Maintained quality standards
- Predictable drug development process
Proposed solution through

- Involving patients in trial design
  - Recruitment & access to directories
  - Outcome measurement – “Real world targets”
  - Better understanding of drug’s performance

- Including functional outcomes
  - Patient-centered data collection – via e- or m-Health

- Easing difficulties related to studies on primates
Topic #3
Knowledge Transfer & Protection of Innovation
Proposed solution through

- Creation of “co-operative research centres”
- Platform to organize exchange of knowledge
- Shift of culture and incentives to Academia necessary
Topic #4
Need for modern 21\textsuperscript{st} century perspective on new tools to assess treatment effects
Current challenges

- Decisions by regulators currently based on tools & scales
  - *Developed in 1970s-80s*
  - *Never updated from latest diseases insights*
  - *Hence no longer scientifically valid…*

- Developing new assessment tool
  - *No agreed biomarkers*
  - *Lack of standardised nomenclature*
Proposed solution through

- Alternative diagnostic tools, eg. cognitive markers
  - Cheap to develop
  - Valid & robust
  - Large database essential to develop & test
  - Provides for “Quality of Life” measurement
Topic #5
Incentivising investment in brain research
Investment in CNS considerably lower than in other fields
Low investment can be explained

- Stigma & under-recognition + Complexity
  
  = No prioritising by governments or companies

- In spite of economic impact (mainly indirect)

- Need to raise profile of huge unmet needs in CNS

& demonstrate cost saving effect
Strong need for

- Stronger Patient Advocacy
- Joint investment strategy
- Awareness raising re.a.o. Cost/Burden & Stigma
Proposed Actions

• Public awareness & patient involvement in
  • Trial design
  • Definition of endpoints
  • Large-scale patient registries

• Linking science & regulation – eg. adaptive trial design

• Update IP Laws to facilitate repurposing & combination therapy

• Leadership on nomenclature, biomarkers & diagnostic tools

• Reproduction and confirmation of preclinical data
Capturing the cost of non-treatment

• EBC-run project – Project outline being defined

• Milestones
  
  Concept note  May 2015
  Internal Roundtable  19th June 2015
  Position Paper
  Public Roundtable  December 2015
  Project & Dissemination

EBC is committed

#Move4YrBrain
How do you intend to contribute?

WE WANT YOU!
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Thank you for your attention !!!