The European Brain Council’s Weekly External Environment Update

Week of 07 April 2014

Quote of the week

The new law will also offer hope to the millions of people in Europe suffering from rare diseases, by making cross-border trials much easier to conduct. There are simply not enough patients in one country alone to develop new or improved treatments for rare diseases. By working at EU level we can reduce the huge cost and burden of conducting trials across borders.

MEPs voted last week to back up a EC proposal on clinical trials and British MEP Glenis Willmott, who led negotiations on behalf of the Parliament lays out the main reasons behind it.

Find out more in Key updates this week section.

Agenda Watch

i) Source: European Commission Comitology Register
Date published: April 4 2014

The Programme Committee for the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) - Configuration ‘Health, demographic change and well-being’ is meeting on April 9 2014. Please find any meeting documents (including draft legislation) and the agenda here.

ii) Source: European Commission Comitology Register
Subject: Minutes – Programme Committee for the specific programme implementing Horizon 2020 - Strategic Configuration – February 5 2014
Date published: April 7 2014

The Programme Committee for the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) - Strategic configuration met on February 5 2014. Please find the meeting agenda below and the summary record of the meeting (including a list of participants) here.

Institution watch

i) On 8 April Angelika Werthmann MEP is organising a high level policy debate on depression at the workplace in the European Parliament in Brussels.

ii) On 12 May eHealth Forum Athens is taking place under the auspices of Greek EU Presidency.
iii) On May 12-13 Active Citizenship Network organises 8th European Patients’ Rights Day:
“The role of citizens’ organisations in the empowerment of patients with chronic diseases”.

Key updates this week

MEPs back new clinical trial rules

New rules will require greater transparency. MEPs voted in Brussels today to back a European Commission proposal to increase transparency and harmonisation of Europe's clinical trials on medicines. MEPs voted 594 to 17 to back a deal reached with member states in December.

Under the new legislation, which will come into effect in 2016, all past and future clinical trials will have to be registered and their results reported. Pharmaceutical companies and academic researchers will have to post the results of all their European clinical trials in a publicly-accessible database.

The new rules will make it easier for these companies and academics to share information about new medicines across borders. Most importantly, the legislation aims to reduce bureaucracy so that clinical trials can be larger, more viable and more reliable.

"The new law will also offer hope to the millions of people in Europe suffering from rare diseases, by making cross-border trials much easier to conduct,” said centre-left British MEP Glenis Willmott, who led negotiations on behalf of the Parliament. “There are simply not enough patients in one country alone to develop new or improved treatments for rare diseases. By working at EU level we can reduce the huge cost and burden of conducting trials across borders.”

Member states agreed to the MEPs’ demand that detailed summaries be published in a publicly-accessible EU database, including full clinical study reports to be published once a decision on marketing authorisation has been taken or the marketing authorisation application has been withdrawn. Fines would be imposed on sponsors who do not comply with these requirements.

In a separate vote, MEPs locked in a first reading position on a proposal to overhaul EU rules on invasive medical devices – those that go inside the human body. Member states remain divided on the controversial subject and have as yet been unable to agree a common position.

With no agreement with member states possible before the end of the parliamentary term, MEPs needed formally to adopt the position agreed in the environment and health committee in September, if they are to bind the next Parliament to work on that basis. MEPs voted 549 to 13 to lock in their position.

EC consultation on mHealth or mobile health.

The European Commission has launched a consultation on mHealth or mobile health, asking for help in finding ways to enhance the health and wellbeing of Europeans with the use of mobile devices, such as mobile phones, tablets, patient monitoring devices and other wireless devices. Consumer and patients' organisations, health professionals and health organisations, public authorities, app developers, telecommunications service providers, mobile device manufacturers,
individuals and all interested parties are invited to respond to the consultation, by 3 July 2014.
Examples of the questions being asked are:
1. What safety and performance requirements should apply to lifestyle and wellbeing apps?
2. Which security safeguards could ensure health data is safe in an mHealth context?
3. What is the best way to promote mHealth entrepreneurship in Europe?

Articles of interest

✓ Public health: Commission stresses need for greater effectiveness, accessibility and resilience for EU's health systems

✓ Policymakers must do more to address depression, argues ME

✓ Fall in demand for European Research Council grants in first Horizon 2020 call

✓ #EUmanagthestress – EU-OSHA campaign calls on employers and workers to tackle work-related stress

✓ EuroHealthNet sees EU Communication on sustainable health systems as challenge for all 2015 -2020

✓ EMA announces final steps for its clinical-trial data policy - Targeted discussions with key stakeholders in May

✓ The only thing more expensive than health is losing it (e-health)

Dates for your diary

2014 meeting schedule: Board Meetings (BM), Industry Board Meetings (IBM), Executive Management Team Meeting (EMT), Telephone Conferences (TC)

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<td>18 July 2014</td>
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Calendar

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<td>23rd European Stroke Conference</td>
<td>6 – 9 May 2014</td>
<td>Nice, France</td>
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<td>Joint Congress of European Neurology (EFNS-ENS)</td>
<td>31 May – 3 June 2014</td>
<td>Istanbul, Turkey</td>
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<td>11th European Congress on Epileptology</td>
<td>29 June - 3 July 2014</td>
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<td>FENS Forum of Neuroscience</td>
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<td>EANS European Congress of Neurosurgery 2014</td>
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<td>27th ECNP Congress</td>
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