



# European Alliance for Personalised Medicine

**EAPM Bulletin: Issue 1, February 2015**

## EAPM set for another busy year

Last year was a non-stop one for the Alliance and 2015 promises to be even busier. Over the past 12 months we have hugely increased our media, policy and political profile, with the launch of the STEP's campaign. The latter has led to the creation of the STEP Interest Group of MEPs in the European Parliament,

Dozens of EAPM-penned articles have appeared in the press, which has attracted a wider audience to the issues that our members have highlighted. Meanwhile, our four active Working Groups and Regulatory Taskforce have produced consensus-driven recommendations being advanced through engagement with the European Commission, Parliament and Council.

On top of this, we hosted a highly successful second annual conference at the stunning Solvay Library in Brussels, presented EAPM to numerous groups and forums, held a key meeting at the ESMO Congress (more of that later) and published several extensive documents including an MEPs' Briefing on Personalised Medicine for the new intake, and a Lighthouse Initiative on the European Data-driven Economy, alongside our conference report and a review of our work since formation in 2012. Find them all here.

2015 will see plenty going on. Apart from the launch of this new, regular newsletter, it was already a lively start for the Alliance in January with meetings organised to discuss the issues around patents and diagnostics; a Big Data Workshop to discuss the Big Partnership Value; a meeting with DG Research to discuss the European Translational Research Platform and a conference organised with the Commission to discuss a possible pilot project on personalised medicine.

The activities will continue with, for example, planning for meetings with the Commissioner for Health and the EU Ombudsman, as well as a stakeholder roundtable with Member States attachés to discuss relevant articles that will have a negative impact on research staying and being undertaken in the EU. But there's more...

EAPM meetings currently scheduled are as follows:

- The Data Protection Workstream will hold a roundtable with Member State attachés - 3 February
- Roundtable event on 25 February in Brussels to discuss reimbursement pathways in personalised medicine
- Patents/Diagnostics: Value of Diagnostic Information in Personalised Medicine, Radisson blu hotel on 25 February, 10:30 - 14:30. Workshop: An innovative approach to collaboration for a healthier EU
- European Parliament, Brussels, 25 February - 14:30 - 17:30. EAPM has worked with its membership to examine approaches to value assessment and the existing perceptions of what constitutes value. This discourse will be picked up in a workshop discussion on the future of companion diagnostic access and innovation in Europe.
- WG on Access and Innovation: Regarding Medical Adaptive Pathway activity - 3 March and 29 May

## New for 2015

### SMART and the June conference

We're already in the second month of the year, with a new rotating presidency at the helm of the European Union. Latvia will be followed by Luxembourg on 1 July and, while these are two of the smaller Member States, they both have big agendas for their terms in office.

EAPM will be working with both presidencies throughout the year to help further the cause of personalised medicine and bring about the goal of delivering the right treatment to the right patient at the right time. Much remains to be achieved.

Latvia says the EU needs to "enhance its entrepreneurial capacity by promoting investment in new and competitive products and services". Of course it does, and investment in research and new medical products, as well as training for

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healthcare professionals in all the new areas opened up by personalised medicine is one way to bring about outside investment as well as a thriving, and effective, health sector. This will aid job creation, while promoting social cohesion.

EAPM believes that health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries and in the regions of the larger ones. We call this a SMART approach – Smaller Member states And Regions Together. This will be further developed at EAPM's third annual conference on 22 and 23 June.

The Alliance is of the view that if the presidencies, the European Parliament and the Commission work in harmony this will improve the quality of life for patients in every country in Europe. [Read the full article here](#)

### **Cancer clinical trials initiative**

Clinical trials are vital to patients and the advancement of cures for myriad diseases, but the issues surrounding countrywide and, even more so, pan-European trials and their application in modern-day medicine are complex.

As a follow-up to a high-level, multi-stakeholder meeting at the ESMO congress in Madrid last autumn, EAPM has taken discussions to the next stage by setting up a Consensus Group on Clinical Trials consisting of multi-disciplinary experts from a broad base of countries across the EU.

The initiative also came on the back of an extensive stakeholder survey carried out by the Alliance.

The consensus panel will attempt to define how personalised medicine cancer clinical trials should be organised to direct patients to the most appropriate research and address important unmet needs.

During the ESMO Congress, stakeholders agreed to try to address how Europe can stay at the forefront of clinical trials in cancer, focusing on personalised medicine. [Read the full article here](#)

### **The European Semester**

One of the newer EU initiatives is the European Semester process. This allows Europe's institutions an intimate overview of EU Member States' economies and forward planning on an annual basis and tasks the European Commission with giving advice and guidance to all 28 countries in the bloc.

Thus far, given that it is such a large budget area in every Member State, the Commission has yet to involve itself in the health arena as much as may have been expected in most countries. Certainly compared to its involvement in health budgets during bailout negotiations.

However, there is a growing belief, and in some cases, desire (certainly within the Alliance) for this to change. This is especially the case when it comes to smaller Member States (and regions within larger ones) that are more vulnerable to imbalances in access to the best healthcare, find it difficult to hear about or get to clinical trials and suffer inequalities in the reimbursement of, and again access to, cross-border healthcare.

EAPM will be focusing on issues surrounding the Semester in five Member States. [Read the full article here](#)

### **The STEPs campaign**

It seems that much is happening that is good and bad in EU healthcare and it would be unreasonable to expect any one presidency to tackle it all. But Europe must act urgently and in concert because, not surprisingly, health and healthcare are among the top priorities for its citizens. The EU's Horizon 2020 and IMI programmes are, of course, working to improve research and healthcare across Europe but more needs to be done.

In line with EAPM's Specialised Treatment for Europe's Patients initiative (STEPs) we therefore call on the EU to commit to the following:

- **STEP 1:** To ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine

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- **STEP 2:** To increasing R&D for personalised medicine, while also recognising its value
- **STEP 3:** To improving the education and training of healthcare professionals
- **STEP 4:** To supporting new approaches to reimbursement and HTA, that are required for patient access to personalised medicine
- **STEP 5:** To increasing awareness and understanding of personalised medicine

### MEP Interest Group

On the back of its STEPs campaign, originally set up to coincide with the 2014 European Parliament elections, the Alliance is taking its work a stage further.

With a new European Commission also in place, the post-election emphasis of STEPs is an Interest Group of MEPs to drive the goal of personalised medicine's integration into an effective and modern EU-wide health policy. This will continue the work originally undertaken with members of the EP during 2012, 2013 and 2014.

Early in its relatively young life as an organisation, EAPM set up an informal working group of cross-party MEPs who supported the Alliance's policy requests during the last legislative period by proposing stakeholder-led amendments in, for example, the areas of Horizon 2020, Data Protection and Clinical Trials.

When EAPM launched the first stage of its STEPs campaign, the goal was to continue the engagement with MEPs, underline what had already been achieved together and, crucially, to ensure that candidates for the elections were aware of EAPM and the issues that the Alliance supports.

In order to keep this hard-won momentum going, the

STEPs campaign will now shift its emphasis towards engaging with newly elected politicians who feel they can support EAPM's multi-stakeholder membership. To this end, the Alliance will be developing a number of policy papers in tandem with politicians in order that needs can be implemented. Read more - <http://www.eureporter.co/economy/2014/12/11/meps-personalised-medicine-interest-group-launches-with-call-for-rules-to-keep-up-with-science/>

A key goal of this group will be to provide a bridge to the national level in order to support the Alliance's Member State affiliates in the areas of, for example, research, cross-border healthcare and healthcare delivery. Such work, EAPM believes, will push the agenda and help hugely to speed the provision of effective results for patients across Europe.

### Policy Taskforces:

EAPM has five policy taskforces working continuously on:

- **Big Data**

Key Task: Focusing on ensuring that there is a 'Lighthouse Initiative' on personalised medicine. Survey the WG regarding why personalised medicine should be a focus, as well as identifying possible focus areas. Continuous engagement with the Commission and broader stakeholders.

- **Education and Training of Healthcare Professionals**

Launching of Personalised Medicine Literacy Survey among healthcare professionals. Finalising a framework for the Summer School.

- **Early Access and Better Decision Making**

Finalising a publication as well as revising the methodology to undertake an activity for access and the EU Semester.

- **Research Roadmap for PM**

Developing the framework for the European Translational Research Platform while consulting with wider stakehold-

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ers including the Commission. Following up on Horizon 2020 projects

• **Regulatory Affairs**

On 25 February, the work stream on In-Vitro Diagnostics - led by the European Diagnostic Medicine Association (EDMA) - will hold a workshop titled 'Value of Diagnostic Information in Personalised Medicine'. The workshop will showcase the different views on the value of companion diagnostics in the broader context of personalised medicine. EAPM has worked with its membership to engage patients, payers, policymakers, academia, and industry to examine various approaches to value assessment and the existing perceptions of what constitutes value. Read more here <http://www.eureporter.co/health/2015/01/06/safety-first-but-ivd-legislation-must-also-promote-innovation-and-access/>

On 3 February, the Data Protection Work stream will hold a roundtable with Member State attachés to discuss articles of the ongoing revision of the Data Protection Regulation and present case studies on how this will impact research developing life-saving treatments .

The Clinical Trials Working Group is monitoring the different activities that the European Medicines Agency is undertaking, while the Medical Adaptive Pathways Workstream is organising a meeting in March.



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**About EAPM**

The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European health-care experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

As the European discussion on personalised medicine gathers pace. EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

The mix of EAPM members provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry. Relevant departments of the European Commission have observer status, as does the European Medicines Agency. EAPM is funded by its members.

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