

# European Alliance for Personalised Medicine

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# Brussels conference coming up fast...

Welcome to the March edition of the EAPM newsletter. As well as the annual conference in just a few weeks, the Alliance will be focusing on new regulations in respect of HTA with an internal meeting on 7 March.

As regular readers will have noted last month, the European Commission issued a new proposal on plans for future cooperation among EU Member States when it comes to determining the added value of new therapies.

Our members' meeting will discuss the issues in a multistakeholder, cross-sectional environment and aim to understand each others' perspectives. More on HTA follows elsewhere in this bulletin.

#### **R&I** and social prosperity

Meanwhile, the Commission has also recently released a report on Research and Innovation Performance in the EU.

Research and innovation (R&I) can have a huge impact on the economy and social prosperity, including in quickly developing arenas such as personalised medicine.

The authors of the report contend that economic growth has returned to Europe, after the financial crisis and the years that followed, but what it calls 'sluggish productivity growth' that has been 'flat for more than a decade' continues to hamper growth that is more robust.

Changes in the innovation landscape have been driven mainly by demographic shifts, such as an ageing population, globalisation and digitalisation.

And, to fully reap the rewards of innovation, investment of substantial economic and financial capacity will be necessary.

The report states, however, that overall, Europe is a global R&I powerhouse and 'the leading economy in terms of public investment in R&D and the number of researchers'.

It is already in the vanguard of scientific productions, while the EU accounts for one-fifth of the world's R&D investment, and 23% of the global public R&D. The bloc boasts more than 1.8 million researchers, the largest number anywhere in the world.

Unfortunately, it fails to invest as much as other economies in business R&D, education and skills development, ICT and economic competences.

# In the pipeline for 2018

- 7 March: Internal meeting on HTA
- 27-28 March: 'Personalised medicine and the Big Data challenge', Sixth Annual EU Presidency conference, Brussels
- 10 April: The Digital Day 2
- 23 April: 'Lung Cancer Screening Moving forward towards guidelines', Sofia
- 19-22 June: Third TEACH Summer School for healthcare professionals, Warsaw
- 26-28 November: Second Annual EAPM Congress, Milan

This needs to change, with the authors stating clearly that the EU needs to boost its investment in intangible assets, while swiftly rethinking public support for R&I, especially for breakthrough innovations.

When it comes to scientific excellence, the regional rankings continue to be solidly led by countries such as the UK, while the Netherlands, Denmark and Belgium also perform well.

Unfortunately though, Central and Eastern European Member States continue to trail behind, which appears to reflect the lower efficiency of national R&I systems in transforming R&D investment into scientific and technological output. This obviously brings down the EU efficiency average in this area.

In essence, the report points out that Europe has a great deal going for it in R&I but needs to up its game quickly. A school report might give the EU 7-out-of-10 with a 'must try harder' comment.

Putting tnew strategies in place will allow Europe to take up a unique opportunity to lead the next wave of breakthrough innovation, especially in areas where digital technology meets the physical world.



## Top man Selmayr a worry for healthcare?

Martin Selmayr (above right), Mr Fixit to current Commission President Jean-Claude Juncker (left), will be the EU's top civil servant after the latter's term ends, it has been announced.

When it comes to health coordination at the EU level, the jury is out on this news, but the Brussels communities are already looking to persuade Selmayr of where value lies and he is a known proponent of a strong economy.

The pharmaceutical industry, for one, will be manoeuvring and looking at problems as well as opportunities in the face of various policy initiatives around pricing and patent protection.

The future role of DG SANTE also throws up questions as the already influential Selmayr moves towards his new, high-ranking position. Watch this space...

# HTA under the microscope

As mentioned earlier, the Commission has launched proposals on Health Technology Assessment (HTA) in which it outlines mandatory use of joint clinical assessments reports, after a three-year transition period.

It could go a long way to allowing necessary medical bodies to catch up with a scientific arena that is moving forward quickly, and EAPM welcomes this move.

By the end of the transition period, "all medicinal products falling within the scope and granted marketing authorisation in a given year will be assessed". This also covers selected medical devices.

The bottom-line is that systems need to catch up with science and the Alliance is in ongoing discussions with MEPs on this topic, as well as looking at HTA in detail in our upcoming meeting.

Under the Commission's proposal, HTA bodies in Member States would be required to use the clinical assessment and "no repetition" of it in their overall processes.

A key aim of the new Commission proposal therefore is to reduce duplicated work across the bloc.

#### Sixth Annual Presidency Conference, Brussels

Our sixth annual conference will, like the first five editions and the inaugural Congress last year in Belfast, pull together leading experts in the arena drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives.

European Commissioners Vytenis Andriukaitis, (Health and Food Safety) and Andrus Ansip (Digital Single Market) will also be joining us.

The theme this year will be 'Personalised Medicine and the Big Data Challenge' and the conference will once again be held in the historic Bibliothèque Solvay in Brussels on 27-28 March.

The draft agenda is available to view, <u>here</u>, and you can register for the event <u>here</u>.

Key topics at the conference will include EAPM's MEGA project, which stands for 'Million European Genomes Alliance' and aims to gather one million genomes from across Europe for research purposes through a coalition of willing Member States. More on that follows...

## MEGA should be mega!

The European Commission has prepared a briefing note which outlines the next steps in any 'coalition of the willing'. This will include the proposed signing of a declaration in April and comes as very welcome news.



6th Annual Conference

# BRUSSELS

Plans for the sixth annual Presidency conference of the Brussels-based European Alliance for Personalised Medicine are already in place for 27-28 March 2018.

The 'Personalised Medicine and the Big Data Challenge' event will be held under the Bulgarian Presidency of the EU, which runs from 1 January to 30 June.

Taking place close to the Brussels seat of the European Parliament, the conference will feature plenary sessions in the afternoon of Day One, followed by a dinner in the parliament that evening and a day-long event on Day Two. The conference will revisit the prestigious Bibliothèque Solvay in Parc Leopold.

The effect on healthcare of Big Data, across many disciplines, will certainly mean that clinical researchers and other healthcare stakeholders and professionals will need to develop new expertise and a different approach. Ongoing training will be vital, but there are many other issues to be discussed.

Given the European Parliament elections, which will be not much more than a year away at the time of the conference, a key goal will be to raise awareness of personalised medicine in respect of current MEPs who will be standing again, and potential new Members.

We would be delighted to have you join us in Brussels.

For more information, please contact the EAPM Office: Denis Horgan, EAPM Executive Director Email: denishorgan@euapm.eu



The availability of genetic data from a large number of individuals increases the ability to investigate questions across many rare and common diseases and in different populations, and also provides more information for understanding the results for clinical care in a patient.

A coordinated, pan-European MEGA project would garner crucial genetic information that could have an immeasurable benefit when it comes to the health of current and future citizens across the EU.

EAPM is now in discussions with Member States to make this dream a reality.

As politicians in the European Parliament have put it, among the goals is to link "existing and future genomic databanks (on a voluntary basis) in order to reach a cohort of one million sequenced genomes accessible in the EU by 2022".

This joint commitment will make it possible to bring together fragmented infrastructure and expertise supporting a shared and tangible goal.

It could also make MEGA a 'Research & Innovation champion'.

The project is in line with the Digital Single Market mid-term review priorities, and supports the realisation of the aims expressed in the Luxembourg EU Presidency's Council Conclusions on Personalised Medicine.

EAPM can confirm that several Member States have already indicated that they find this project of special interest to them - a 'mega' step forward.

### **Moving forward in Milan**

The second annual EAPM-run Congress will take place in **Milan from 26-28 November** at the prestigious MiCo venue (above), and we hope to see you all there. The report from last year's Congress in Belfast is available online, <u>here</u>.

More than 1000 Life Sciences thought leaders will convene at the Congress and, as it did last year in Belfast, the event will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange.

Don't miss the opportunity to join large numbers of industry professionals, government regulators, patients, researchers, academia, healthcare professionals, journalists and exhibitors to drive insights to action.

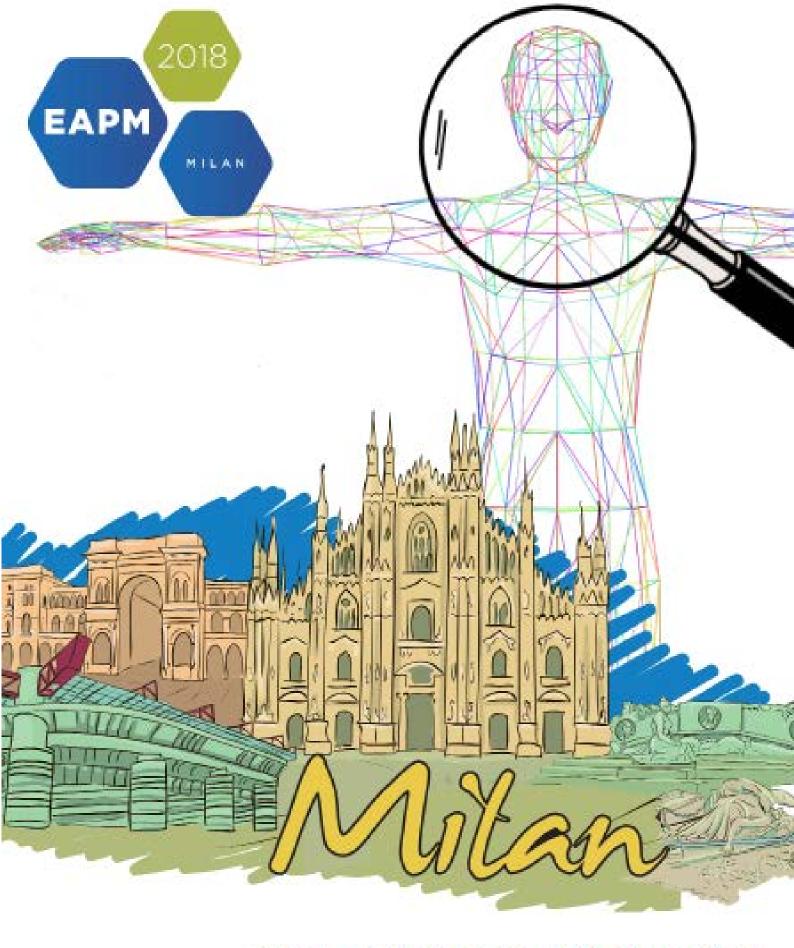
More than ever this year, a focus will be on the upcoming European Parliament elections and the installation of a new College of Commissioners, tasked with devising and implementing regulatory frameworks in all areas, including certain aspects of health.

More than 700 MEPS will be elected next summer and the Commission will also have a new president as Jean-Claude Juncker steps down.

One of the goals of Congress is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process.

#### Third Summer School heads to Poland

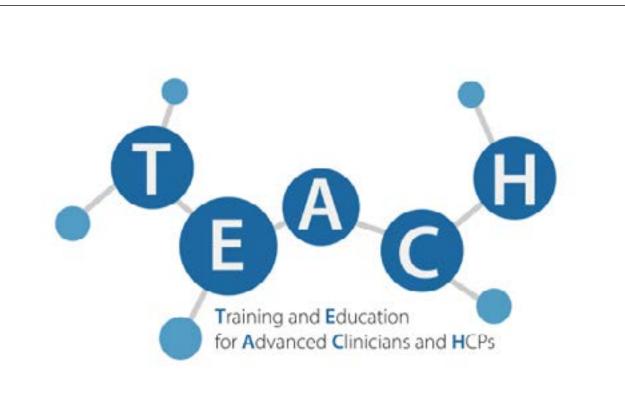
EAPM's third annual Summer Summer School will be held in partnership with the Polish Alliance for Personalised Medicine and will take place in **Warsaw from 19-22 June**.



2nd European Alliance for Personalised Medicine Congress



26 - 28 NOVEMBER 2018 MILAN | ITALY



The title of this year's edition is *New Horizons in Personalised Medicine*.

Among other highlights, the school will feature a lecture devoted to human genetics, ethical aspirations and its role in medicine.

The week will also see coverage of the basics of molecular biology and a workshop on molecular diagnostics, plus topics involving personalised medicine and its different perspectives, colorectal cancer, haemato-oncology, lung cancer, radiotherapy and pathology diagnostics.

Once again, the school will come under the banner of 'TEACH', which stands for Training and Education for Advanced Clinicians and HCPs, and the goal is to bring young, front-line professionals up-to-speed with fast-moving developments in the field.

If personalised medicine is to be in line with the EU principle of universal and equal access to high-quality healthcare, then clearly it must be made available to many more citizens than is currently the case. Ongoing HCP education can help to make this hjappen.

#### In the news

As ever, the Alliance has been busy engaging with the media. Below you can find links to recent articles.

More cooperation needed to make HTA truly effective

How Horizon 2020 is acting to advance personalised medicine

Saving lives through Big Data collection and usage



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#### **About EAPM**

The European Alliance for Personalised Medicine (EAPM), launched in March 2012, brings together European healthcare 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 EMA. EAPM is funded by its members.

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