

European Alliance for Personalised Medicine

EAPM Bulletin: Issue 9, November 2015

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EAPM makes the most of Autumn schedule

Welcome to the November issue of EAPM's newsletter. The clocks may have gone back but the Alliance is, as ever, moving forwards.

Our next conference (Spring 2016), to be held under the EU presidency of The Netherlands, will have as its theme 'Taking Stock'. With this in mind, executive director Denis Horgan recently conducted interviews with key stakeholders at the ECCO/ESMO congress in Vienna.

The discussions covered how personalised medicine has advanced diagnoses and treatments in particular disciplines, where we go next in the field of personalised medicine and whether Europe, in the form of the Commission and Parliament, could play a broader role in healthcare.

Three of these interviews are now online for you to view, with more to follow. Just click on the names below.

[Ian Banks](#) - President of the European Men's Health Forum
[Hendrik van Poppel](#) - Chairman of the Department of Urology at the University Hospital Gasthuisberg, Leuven
[Roberto Salgado](#) - Pathologist and EORTC representative

Over the course of the congress, the Alliance held a workshop and several meetings in an environment that has seen personalised medicine make great strides in the area of oncology.

The workshop discussed how Europe should respond to challenges concerning optimising research to better address the objectives of different stakeholders with competing interests, to make the most of opportunities to address important clinical questions, and to increase multi-stakeholder collaborations, especially cross-border.

It also sought ways to better incentivise development of biomarkers that can accelerate personalised medicine, and to optimise information sharing regarding existing research to avoid decision making that can delay the implementation of best practices in clinical research and its application. Read more [here](#)

Coming up in November:

- 1-2 November: Global Health Forum, Taiwan
- 6-7 November: Annual conference of EUpancreas, Cluj-Napoca, Romania

EAPM focus on the Internal, Brussels

- Internal Meeting on Big Data
- Internal Meeting on Translational Research
- Internal Meeting on Education of Healthcare Professionals
- Internal Meeting on Access/Value of Innovation
- Internal Meeting on Regulatory Affairs

In the pipeline

Clinical trials and more

Meanwhile, after an October meeting to finalise details, a special supplement written by EAPM stakeholders on the subject of clinical trials will appear in *Public Health Genomic* with the title of 'Getting Personal: Accelerating Personalised and Precision Medicine Integration into Clinical Cancer Research and Care in Clinical Trials'.

This will be published in November.

As well as this work, the Alliance is taking part in the public consultation on the preliminary opinion recently released on "Access to health services in the European Union". This has been drafted by a European Commission Expert Panel tasked with identifying effective ways of investing in health. EAPM held a stakeholder meeting in late October to finalise its response.

The preliminary opinion addresses barriers to accessing health care and explores policy measures that can overcome them. Ways to improve equity could include matching health needs and financial resources, affordable and accessible



health services, the availability of a sufficient number of health workers with the right skills, well-equipped facilities within easy reach, the availability of quality medicines and medical devices and services that are relevant and cost-effective.

EAPM has highlighted several areas in the draft report that the Alliance and its stakeholders consider could be clarified and improved.

Trilogues

Trilogue meetings are now being held on a regular basis, so this has been a key time to show the institutions the support behind EAPM's position. The institutions seem to be working to Parliament's proposed timetable, with the next trilogue meeting scheduled 11-12 November.

So far, the Council, Commission and Parliament have managed to reach agreement on approximately 70-80% of the text discussed. It appears that certain political issues remain, for example, the form and conditions of consent, duties to inform data subjects, and the use of standardised symbols for this.

It is still realistic to conclude the agreement before the end of the year, including the discussions on research (A.81/83) towards the end of November. Other clauses relating to research are already under discussion.

Read more [here](#)

Diagnostics experts meet to keep IVD rules in focus

An EAPM-run high-level meeting on in vitro diagnostics took place in Brussels in September, which focused on proposed EU regulations for IVD devices and took an overview of the 'state of play' and the consequences of new rules.

Overseen by Helmut Brand, the Alliance's co-chair, the meeting featured input from the European Parliament, the Commission, EDMA, EORTC, patients' representatives and the European Society of Pathology, among others.

From the meeting, the Alliance formulate the following statement:

EAPM calls on legislators from the European Parliament, European Commission and the Council to:

- Ensure patients have access to safe and reliable IVDs in a timely manner;
- Define companion diagnostics appropriately to reflect the small number of IVDs that play a unique role in choosing patients that are suitable or unsuitable for a specific therapy;
- Exclude special treatment for in-house assays except when no appropriate CE-marked product is available and existing loopholes are closed;
- Define clear and proportional requirements for IVD devices used for 'Distance Sales';
- Account for the specificities of companion diagnostics and other IVDs to ensure appropriate and proportionate requirements on clinical evidence, transparency, and the transition period, and;
- Maintain an attractive and competitive environment for innovation in the diagnostic area, especially considering the future competitiveness of the many European SMEs developing new diagnostic test, platform and providing diagnostic services.

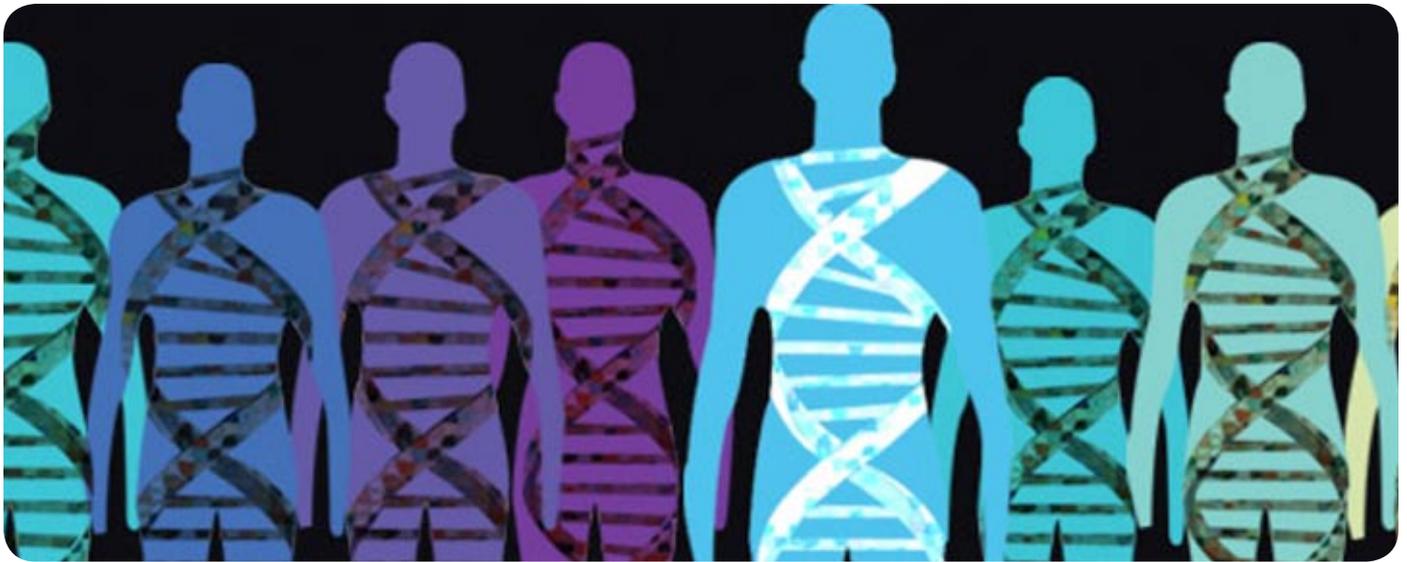
Read more [here](#)

Outreach event

The 8th of October saw a workshop take place in Sofia, Bulgaria, co-organised by the Bulgarian Personalised Medicine Association and EAPM.

Entitled "*Personalised medicine – the right treatment for the right patient at the right time*", this inter-institutional discussion formed part of EAPM's SMART Outreach programme, which will see 'on-the-ground' events in several EU countries over this and the coming years.

This particular workshop addressed key points such as how to improve and accelerate implementation of personalised medicine in Bulgaria.



EAPM's June 2015 conference introduced the Alliance's 'SMART' concept, which stands for Smaller Member States and Regions Together, and EAPM is expanding this by taking its message to other EU countries.

The huge advances in personalised medicine over the past few years (and rapidly rising awareness of this new way of diagnosing and treating patients) led to the Luxembourg Presidency of the EU holding a high-level conference on the topic, the results of which will form part of the Duchy's Council Conclusions at the end of this year.

This constitutes a great leap forward for all stakeholders, most notably the patients themselves. The question now is how to apply these advances to the health system in Bulgaria.

Read more [here](#)

Back at Bad Gastein

At the annual EHFG event in Gastein, EAPM organised a meeting around medical adaptive pathways for patients (MAPPs) as well as having speakers participating in other sessions.

At Bad Gastein, the EU's health policy community gathers each year to tackle issues in the health arena and EAPM organised several sessions at the 2015 event.

Speaking at the event, Stanimir Hasurdjiev, a board member of the European Patients' Forum, said: "Today's patients are more knowledgeable than ever before and should be placed at the centre of their own healthcare decisions.

"Empowering the patient is, and always will be, a fundamental pillar of personalised medicine."

He was backed by Luís Mendão, vice chairman of the European AIDS Treatment Group, who said: "You cannot treat a patient properly without taking into account his or her perceptions of value, you cannot treat a patient properly without taking into account that patient's lifestyle and you cannot treat a patient properly without creating equal access across the EU to the best possible treatments available."

Chris Hoyle, director, Health Economics & Payer Analytics, AstraZeneca said: "Making healthcare systems accessible and affordable to all patients, regardless of personal circumstances and location, should be a cornerstone of the EU's pledge for equality for all citizens. At the moment, we are a long way off that."

Read more [here](#)

Pathways to Personalised Medicine

On 20 October, EAPM held a high-level workshop on rewarding innovation, featuring around 70 stakeholders and including representatives from Member State government, the European Parliament and the Commission.

As well as Belgium's Health Minister Maggie De Block and former Health Commissioner Byrne, speakers at the meeting included AstraZeneca Executive Vice President Europe Ruud Dobber; Philippe de Backer, MEP; Bengt Jönsson, vice chairman of DG Sante's expert panel on effective ways of investing in health; Christian Siebert, head of unit, Biotechnology and Food Supply Chain, DG GROW; Professor Dr. Walter Van Dyck, Vlerick Business School, and Robert Johnstone, of the European Patients' Forum.

At the event, Maggie de Block emphasised that personalised medicine represents the dawn of an exciting new age in healthcare, but also that health-care systems and thinking will need to change accordingly.

She said: "Making access to personalised medicine, a reality for patients is ...a call for action addressed to creative policymakers in order to take the necessary initiatives to allow for more effective early diagnoses, safer, better and tailored treatments for patients."

Read more, [here](#)

The work continues...

Aside from the events and activities outlined above, EAPM continues to engage with MEPs and Commission officials, especially those at DG Sante, DG Connect, DG Grow and DG



SMART

Smaller Member States And Regions Together

Research, on behalf of the Alliance's different, and very active, Working Groups.

In the news...

Several EAPM-penned articles have appeared recently in the media. Simply click on the links, below.

[Europe must guard against knee-jerk reaction on health data, post-ECJ ruling](#)

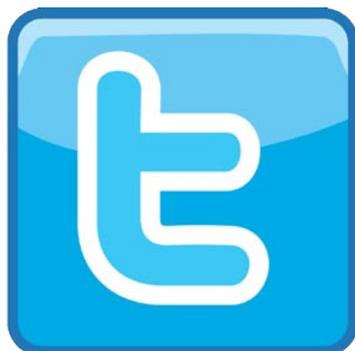
[Trilogue talks must strike balance between data protection and vital health research](#)

[Time for treaty changes and a joined-up approach on EU health](#)

Twitter

EAPM is now active on Twitter.

You can find us [here](#)



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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