European Alliance for Personalised Medicine

EAPM Bulletin: Issue 8, October 2015

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EAPM spreads the word far and wide

Greetings to all EAPM members and colleagues. Here's hoping that September was a busy and fruitful month.

It certainly was for the Alliance with meetings in Vienna and Poland plus several gatherings in Brussels.

And there's much more to follow...

In the pipeline

Medicine's Adaptive Pathways to Patients webcast

On 30 September, EAPM will be present, once again, at the European Health Forum Gastein.

The Forum will serve as the backdrop to an EAPM-organised webcast on 'New paths to personalised medicine: How Medicine's Adaptive Pathways to Patients (MAPPs) and breakthrough designation will impact patients'.

While the long-awaited promise of personalised medicine is finally arriving, the regulatory structures required for their evaluation and reimbursement are still based around the blockbuster models of the last century. This live webcast session will focus on MAPPs in Europe and breakthrough designation in the US – two new approaches to regulatory evaluation that are being implemented and investigated.

Gordon McVie, EAPM Secretary will look at what tools and regulatory methods we need in Europe to move personalised medicines forward, and how the Alliance is facilitating that, which will culminate with the Council Conclusions on personalised medicine, due at the end of the year under the Luxembourg Presidency of the EU.

Other speakers include Chris Hoyle, Director, Health Economics & Payer Analytics (Oncology), AstraZeneca, Carole M Longson, Director Centre for Health Technology Evaluation, NICE; plus Barbara Kerstiens, Head of the Public Health Section, Health Directorate, DG Research and Innovation (DG RTD), at the European Commission.

Coming up:

- **30 September: Webcast on 'New paths to personalised medicine: How Medicine's Adaptive Pathways to Patients and breakthrough designation will impact patients'. This will be broadcast from the European Health Forum Gastein**
- **8 October: Workshop 'Personalised medicine – the right treatment for the right patient at the right time'. Sofia, Bulgaria**
- **20 October: Workshop on rewarding innovation, featuring representatives from Member State government, the European Parliament and the Commission. Brussels, Belgium**
- **Mid-October: Clinical Trials Working Group conference call (date to be arranged)**

Outreach event

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

Titled "Personalised medicine – the right treatment for the right patient at the right time", this inter-institutional discussion forms 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 will address key points such as how to improve and accelerate implementation of personalised medicine in Bulgaria.

The government of Bulgaria took the responsibility of performing a huge reform of the healthcare system, based on in-depth analysis of the reasons which have led to the poor health indicators of the country.

It sets long-term strategic goals aimed at ensuring better health for Bulgarian citizens. The changes concern almost all spheres, which affect the health of the population and put healthcare provision on new ground.

The process aims to fully guarantee the best possible

healthcare for all citizens yet it requires restructuring the activities, financial and human resources of the country.

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. These have already included Poland and Austria.

EAPM believes it is time to place its feet firmly on the ground in more EU countries, in order to expand its work with the multi-stakeholder groups, and nations, that form its membership.

Pathways to Personalised Medicine: Rewarding innovation in times of budget constraint

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

This inter-institutional discussion, at Brussels Press Club Europe, will reflect the Alliance's multi-stakeholder and patient-centred approach by including attendees and speakers from industry, academia, various policy-making bodies, science, research and, of course, patients.

For example, speakers at the Brussels event will include Maggie De Block, Belgium Health Minister (TBC); Ruud Dobber, Executive Vice-President Europe, AstraZeneca; Bengt Jönsson, Vice-Chair of DG SANTE's expert panel on effective ways of investing in health; Prof. Dr. Walter Van Dyck, Vlerick Business School, and; Robert Johnstone, EPF Board member.

The former European Commissioner for Health and Co-Chair of EAPM, David Byrne, will chair the event's Q&A session and will set the scene with his opening remarks.

This meeting will also form part of EAPM's SMART Outreach programme, which will see 'on-the-ground' events in several EU countries over this and the coming years.

EAPM 4th annual Presidency conference

EAPM's fourth annual conference, in Spring 2016 under the EU Presidency of The Netherlands, will have 'Taking Stock' as its over-arching theme.

The two-day event, to be held at the Solvay Library in Brussels, will take as its format an opening plenary followed by five further sessions. As for the past three conferences, thesel include a powerful array of high-level speakers and will be attended by some 180 experts.

More details to follow.

Busy September

Summer School for HCPs

On 8 September, the Alliance held a full-day meeting in Brussels, with the objective of establishing an education curriculum for healthcare professionals (HCPs) dealing with necessary elements concerning personalised medicine.

The school will aim to attract many of Europe's leading HCPs in order to develop, deliver and encourage uptake of personalised medicine, by building on practical approaches through an agreed curriculum.

The objective is for HCPs to learn, share and develop and the focus at this meeting will be on several areas such as diseases and genetic markers, 'omics technologies and imaging markers, among others. It is envisaged that the Summer School will take place either in June or July of next year.

Modernising clinical trials

On 25 September, as a side-meeting of the ESMO-ECCO congress in Austria, EAPM held a second annual event on clinical trials to build on the work from last year, and its high-level meetings held in between.

This was the 18th ECCOand the 40th ESMO European

EUROPEAN CANCER ORGANISATION

Cancer Congress and the largest event this year to present new data and ground-breaking information to oncology professionals.

The EAPM meeting, at the Nestroy Hotel in Vienna, sought to priortise several issues, and possible solutions, identified by the Alliance and its partners on key policy asks that the oncology community should focus on for the next two years.

Speakers included patient representative Francesco de Lorenzo, members of ESMO, and EAPM's executive director Denis Horgan.

Among the key issues addressed in Vienna were finding ways to optimise research to better address the objectives of different stakeholders with competing interests, optimising the finite opportunities to address important clinical questions in research, increasing cross-border collaborations especially among different stakeholders and incentivising the successful development of biomarkers.

Other discussions covered what solutions can be offered to optimise information sharing regarding existing research to avoid suboptimal clinical decision making. The latter can delay the implementation of best practices in clinical research and practice.

Diagnostics experts meet to keep IVD rules in focus

A high-level meeting on in vitro diagnostics took place in Brussels on 14 September involving key stakeholders from across medical disciplines and several EU Member States.

The meeting focused on proposed EU regulations for IVDs and took an overview of the 'state of play' and the consequences of new rules for stakeholders.

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

The meeting heard that the revision of the EU's In Vitro Diagnostics Directive presents an opportunity for strengthening the current approval system for IVDs for the sake of patient safety, competitiveness and innovation.

IVDs, especially companion diagnostics, play an essential role in personalised medicine and the patient-healthcare pathway. As non-invasive tests used for diagnosis, screening, assessing predisposition and monitoring, IVDs do not treat patients; instead, they rely on biological samples, including blood, urine or tissue, to provide a specific set of data regarding an individual's health status.

With this in mind, there are characteristics of IVDs that distinguish them from medical devices and pharmaceuticals.

Within the IVD sector, companion diagnostics consist of highly innovative and precise tools that necessitate special consideration of these integral components of the further development of personalised medicine.

Specifically, the meeting heard that the definition of IVDs is not specific enough and should only include those IVDs selecting patients for specific therapy.

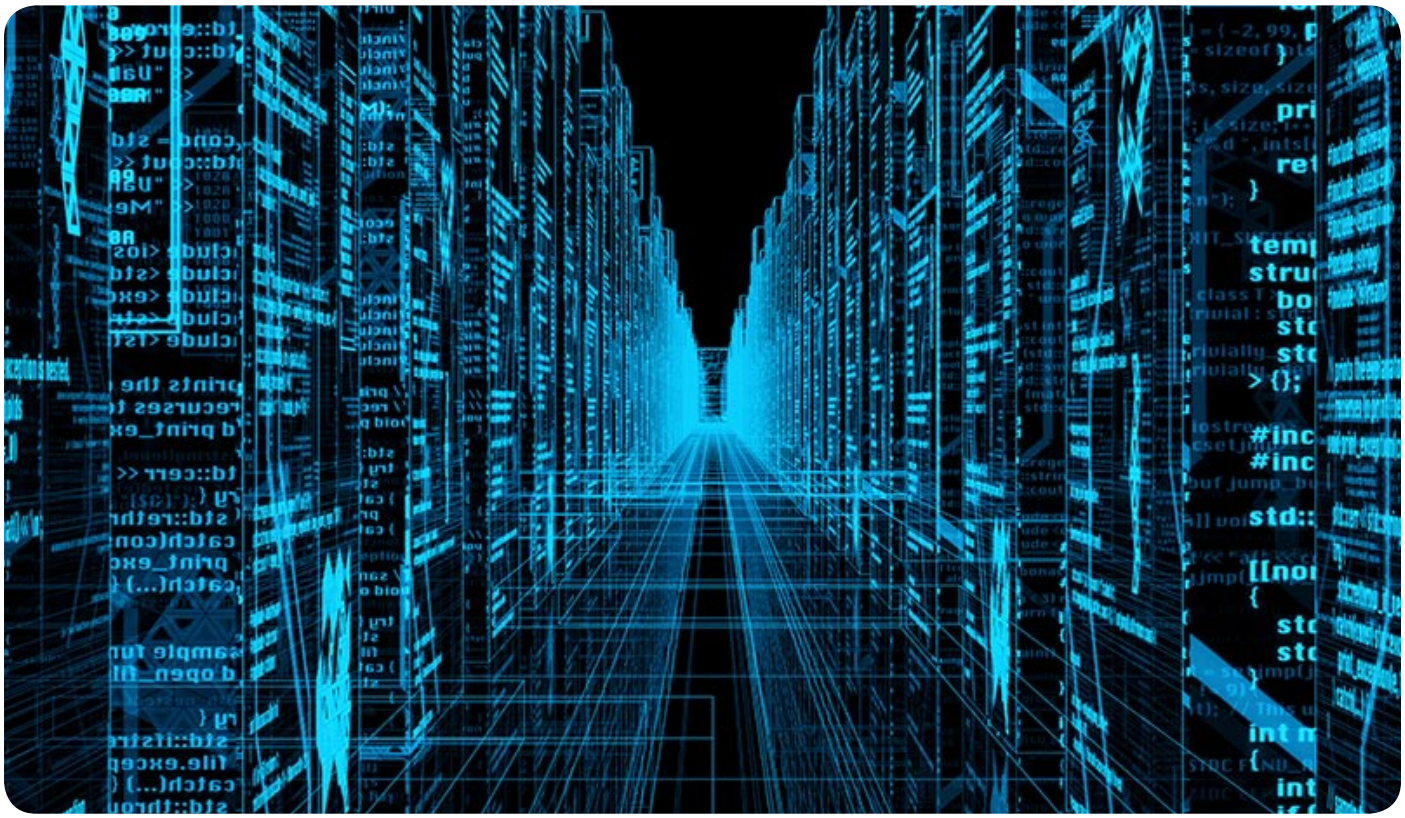
Attendees heard that the definition of companion diagnostics should reflect "the small subset of devices that are truly acting as gatekeepers for advanced therapies". The European Parliament proposal constitutes a good definition, though further guidance may be needed in secondary legislation.

The meeting supported the notion that a five-year transition period is needed for manufacturers to be able to fully comply with the various new requirements and place all necessary manufacturing processes in place.

Health Data Taskforce initiative

EAPM has for some time included within its range of Working Groups a Health Data Taskforce.

In September, the Alliance officially requested that the European Commissioner for Health and DG Connect should bring forward their own proposal for a multi-stakeholder platform to oversee the implementation of the General Data



Protection Regulation. This follows the commission's own communication calling for: 'A comprehensive approach on personal data protection in the European Union.'

EAPM believes that such an approach should take the form of an official Joint Action on Data with contributions from all stakeholders. This would be a valuable resource for the European Commission in these fast-changing times.

The Alliance also believes that Europe needs a responsive system of regulation that offers high levels of protection for individuals and high-quality data access for researchers.

In the news...

Over recent weeks, a series of EAPM-penned articles have been published. Click on the links below to read them.

Europe must act to keep pace with Obama initiative

Modernising clinical trials for the benefit of Europe's patients

Male life expectancy and the battle against prostate cancer

White Paper launched in fight against pancreatic cancer

30 years and counting: Where next in battle against cancer?

Don't let Europe's health sail into the sunset

Making the most of the personalised medicine revolution

Four 'tensions' for personalised medicine to ease

Effective, affordable cancer treatments are one step nearer

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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