

European Alliance for Personalised Medicine

EAPM Bulletin: Issue 5, June 2015

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Third Annual EAPM conference and more

In the pipeline

Welcome to our latest newsletter. As well as the great deal of time and work spent on the organisation of the Alliance's **third annual conference**, which runs from 2-3 June, we are also following developments in several key areas.

As highlighted recently by EAPM, Belgium and The Netherlands are to join forces in a bid to negotiate a better deal for smaller countries when it comes to the price of medicines. We had also heard that it was possible that Luxembourg would join the pair, but the latest word (as this newsletter was finalised) is that this will not be the case.

But given that the upcoming Luxembourg EU presidency will be immediately followed by The Netherlands - on 1 January, 2016 - we're likely to hear much more about this exciting collaboration between the Dutch and Belgians.

Meanwhile, MEP Philippe De Backer has tabled an updated plan for a fund for joint purchasing of 'orphan drugs' - so named as they deal with rare diseases, treat limited amounts of patients and are, thus, very expensive.

The idea is to get Member States to contribute to one joint fund to pay for the medicines and De Backer has already had contact with those high up in the cabinet of the health Commissioner Vytenis Andriukaitis.

Clearly Member States - who will put up the cash - need to be persuaded, but it seems that plenty of politicians, researchers and drug companies may be open to the plan.

Elsewhere, the EU medical device regulation - on the table for the past three years - will be the topic of a formal discussion among health ministers at a Council meeting on 19 June, and already officials from Member States have been meeting in advance to thrash out any differences of opinion.

Meanwhile, in the area of the Single Market, there is talk of a new EU expert panel to set minimum standards for innovative devices used in brain, joint and circulatory

June and July at a glance:

- 2 June: Press conference on the launch of the PerMed SRIA, Brussels
- 2-3 June: EAPM annual conference on Smaller Member States And Regions Together (SMART), Brussels
- 17-19 June: Alliance parallel meeting at the Big Value Data Association summit, Madrid
- 1 July: Clinical Trials round table to build on the work of our Working Group, Paris
- 8 July: Luxembourg Presidency conference on Personalised Medicine, Luxembourg

conditions. This has been put forward - and pushed - by France, although Germany is thought to be stalling.

In any event, such standards would not be mandatory, but it seems that firms would have to justify not abiding by any new guidelines.

Big Data meeting

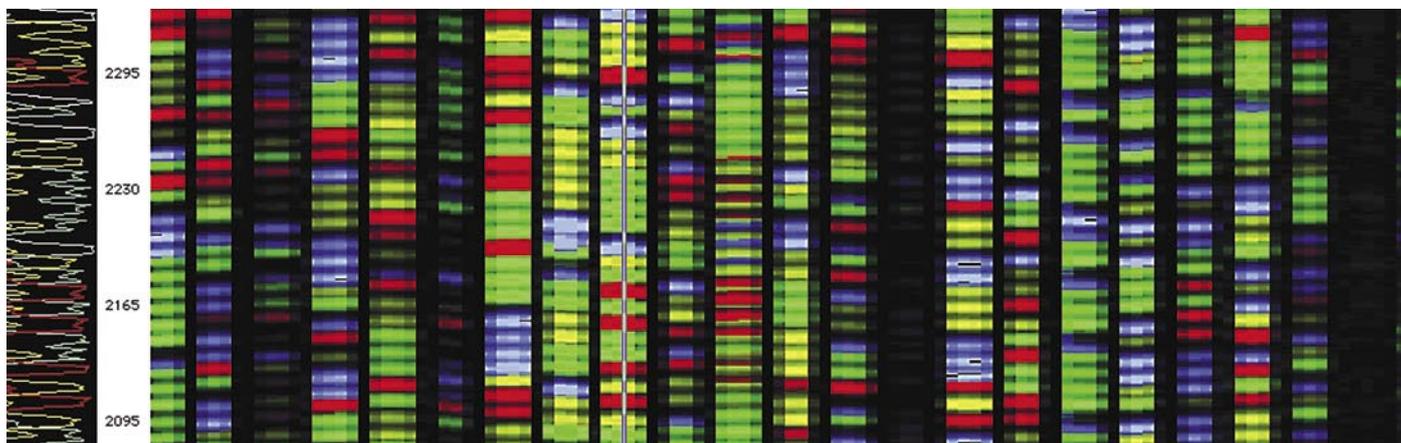
During the final week of May, EAPM took part in a Big Data meeting, with our attendees including Ernst Hafen, Angela Brand, Mario Romao (leader of our Working Group on Big Data) and Executive Director Denis Horgan.

The round table was organised in close association with EFPIA and DG CONNECT.

The latter is working on a follow-up to the adoption of the Commission Communication entitled 'Towards a thriving data-driven economy'.

The Commission is gathering input from stakeholders on how the EU can support the development of a data-friendly business environment.

The results of consultations with major industry players will contribute to the development of an action plan by the EC for Europe's data economy this year.



At this meeting the main issues addressed were:

- The use of Big Data to improve operations (both strategic decision-making and development & production processes) as well as the products and services they offer
- The emergence of cooperation environments among several industrial actors (including SMEs) and/or academic institutions that may turn into ecosystems of continued cooperation
- The presence or absence of certain enabling framework conditions such as computing infrastructure (including software) and skilled staff
- Innovative approaches to dealing with personal information, including data security and the issue of ownership of data

During the meeting EAPM set forth the novel idea of Data Cooperatives, a topic in which Ernst is an innovator and expert.

Meanwhile, the first **Big Data Value Association** summit will take place in Madrid on 17-19 June (click [here](#)) and EAPM will organise a session on our action plan priorities, during one of the parallel sessions on 18 June.

During the closing session, an Alliance speaker will highlight EAPM's key points, which will go towards the final outcomes.

Upcoming EAPM activity

On Tuesday and Wednesday 2-3 June, EAPM will host its **annual conference**, focusing on smaller Member States and regions, and we are delighted to confirm the presence of the Luxembourg Minister for Health, Latvia's Secretary of State for Health and Malta's Parliamentary Secretary for Health, alongside representatives from several relevant European Commission Directorates-General. For the up-to-date programme, click [here](#).

The two-day event will take place at the **University Foundation** in Brussels and will be preceded by a press conference (2 June) to launch **PerMed's Strategic Research and Innovation Agenda (SRIA)** report.

The press conference will begin at 11am, and the report

will be outlined by MEP Marian Harkin, PerMed Coordinator Dr. Wolfgang Ballensiefen and patients' representative Louis Denis. Rudolf Strohmeier, Deputy Director General at DG Research and Innovation, will also speak, with EAPM present in its role as a PerMed partner.

"There is a distinct need for much more coordination when it comes to research policy in the EU," said MEP Cristian Busoi. "At the moment there is far too much fragmentation and duplication, wasting valuable time and resources, and slowing down innovation."

The Parliament's Marian Harkin added that: "Targeted investment in medical research needs to be stepped up, and Big Data issues solved, if we are to unlock the potential of personalised medicine for the benefit of all 500 million citizens across 28 Member States."

PerMed is a Coordination and Support Action (CSA) of 27 partners, financed by the European Commission and representing patients' interests as well as decision makers in research policy, health care and implementation.

It is tasked with generating recommendations and research activities aimed at fostering the further implementation of personalised medicine – a fast-emerging method of treating patients on an individualised basis that is largely based on genetic make-up.

The SRIA to be presented on 2 June is based on an analysis of several recent strategic reports, plus interviews and consultations with experts and representatives of all relevant stakeholders in the arena of personalised medicine.

It has examined current challenges before suggesting prioritised recommendations with the highest potential for facilitating the introduction of this exciting new form of treatment.

The report's recommendations include an urgent need to: demonstrate the impact and potential benefits of personalised medicine for health systems, by supporting public health evaluations; incorporate patient participation and responsibility in all phases of research and development and in the ownership and control of personal health data, and; develop common principles and regulatory frameworks that enable the ethical sharing of personal data for research.



SMART

Smaller Member States And Regions Together

Other recommendations highlight the need to: promote the development of high-quality sustainable databases; support translational research infrastructures and enforce data harmonisation; develop new decision-support tools and methodologies to analyse and interpret data, and; better integrate and evaluate information provided by genomic, epigenetic, transcriptomic, proteomic, metabolomic and micro-biome analyses.

Also vital is the development of new clinical trial designs as well as a systematic early dialogue between innovators, citizens and decision-makers throughout all regulatory steps.

These recommendations will be described and explained further at the press conference.

EAPM has also called for the development of a European Translational Research Platform (ETRP) that enables the efficient conversion of exciting research discoveries to innovative diagnostics, therapeutics, products and processes that will benefit European patients, industries and societies.

City of Lights

EAPM will hold a meeting in Paris on 1 July on the subject of clinical trials, building on the work of our Clinical Trials Working Group.

During May, there were numerous conference calls held between the participants, and the Paris rendez-vous will bring about a constructive face-to-face encounter involving the group's members.

The Paris meeting's agenda will be circulated to EAPM members in early June.

Luxembourg takes the helm

As mentioned earlier, on 1 July, Luxembourg will take over the EU's rotating presidency. The Duchy has already announced that personalised medicine will play a key role in its agenda and the first fruits of this will be seen at a **Presidency Conference** in Luxembourg City on 8 July.

The conference aims to do the following:

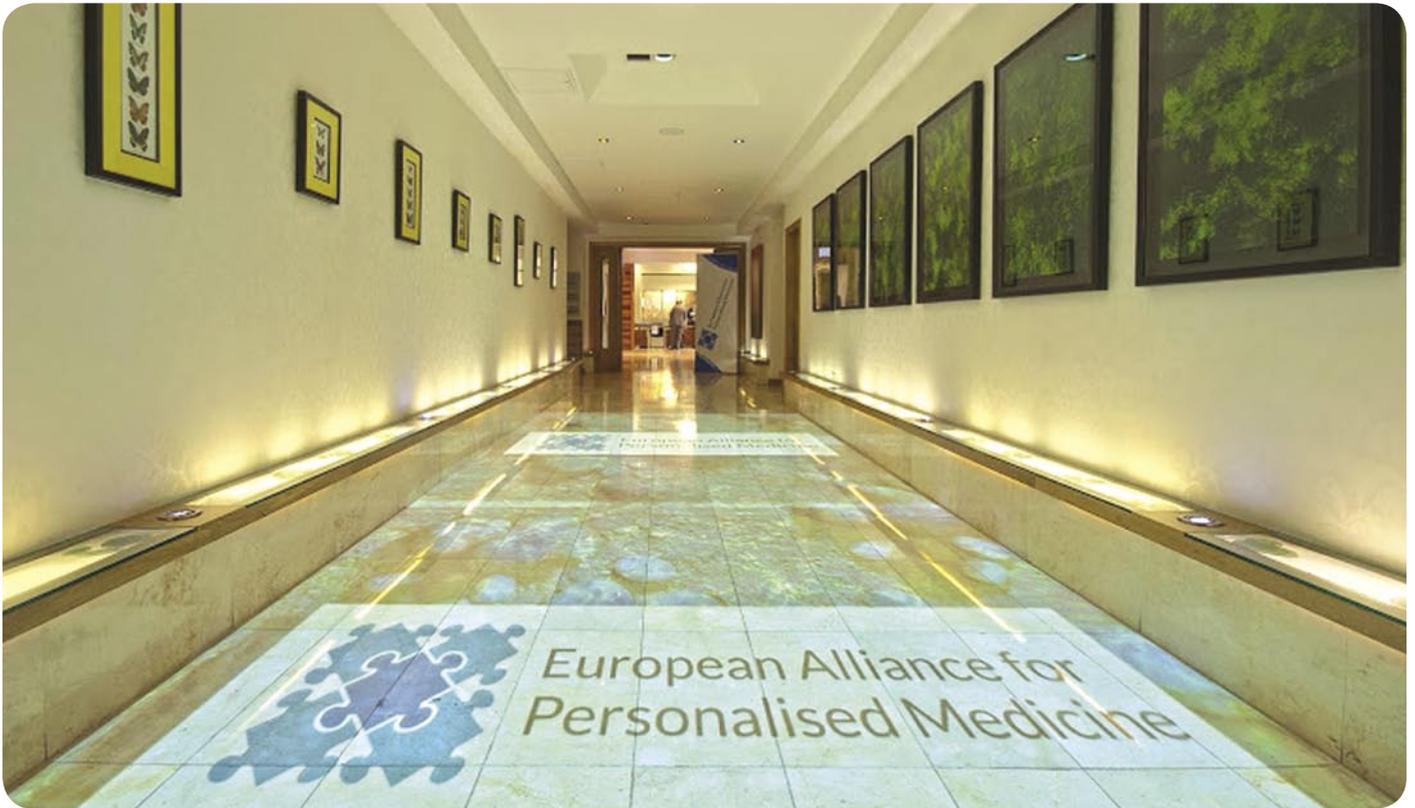
- Assess and address obstacles to the integration of personalised medicine into Europe's healthcare systems
- Identify best practices and the added value that such an approach can deliver
- Outline the potential benefits that a personalised medicine approach could have on public health and its impact on policymaking in the EU

The conference's main messages will form part of Council Conclusions to be adopted by the 28 health ministers during the December EPSCO Council.

Question Time

As well as a presentation of preliminary results of the EAPM and EHA joint-survey on education in the arena of personalised medicine at the EAPM conference, the coming weeks and months will see follow-ups of surveys being disseminated at various stakeholder congresses.

The first of these will take place at the EHA Congress on from 9-12 June.



Read all about it...

As regular readers will be used to by now, during the past weeks and months, the Alliance has been working to spread the word and explain the benefits of personalised medicine to the wider world.

A number of our recent articles can be found by clicking on the titles below.

- 'Big Data' should have patient welfare at its heart
- Timmermans' 'Better Regulation Plan' is a step in right direction
- 100 million potential patients 'not well-informed' on cross-border health options
- Health-care spending cuts are false economy
- Governments come and go, but health remains the big issue
- Digital Strategy: Putting patients at the heart of the EU agenda
- Affordable health care in testing times: The way forward

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.

*Contact: Denis Horgan
EAPM Executive Director
Avenue de l'Armee/Legerlaan 10
1040 Brussels, Belgium
Ph: + 32 4725 35 104
Website: www.euapm.eu*



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