European Alliance for Personalised Medicine

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Alliance at UN General Assembly, NYC

Welcome to EAPM's October newsletter. We have exciting news of a recent event in New York when the Alliance held a meeting at the 71st United Nations General assembly.

Project New York

The former European Commissioner for Health, David Byrne (also EAPM co-chair), told the high-level forum at the UN on 23 September that access for patients to medicines that efficiently treat illness must be addressed on a global scale.

The Alliance's event and the UN event, organised in conjunction with the Irish and Austrian Permanent Missions to the UN, took the form of a high-level workshop ahead of further discussions in the afternoon (see photos on pages 2,3 and 4).

Topics covered at the event - called '*Taking Stock – The role of science to realise a healthier world*' - included health literacy and guidelines, clinical trials and data protection, and the implementation of genomics into healthcare systems.

Speakers included the Alliance's other co-chair Professor Gordon McVie, who represented EAPM alongside former Commissioner Byrne and executive director Denis Horgan.

Also speaking at the EAPM event were Marisa Papaluca who is Senior Scientific Advisor, Human Medicines Research & Development Support Division, at the European Medicines Agency, alongside E. Abrahams, President of the Personalised Medicine Coalition, A. Dickinson, Senior Vice, President of Strategic Initiatives, Illumina.

They were joined by K. Paranjape, General Manager Life Sciences and Analytics, Health Strategy and Solutions Group at the Intel Corporation, Jan-Eric Litton, Director General BBMRI-ERIC and Steve Canfield, Guidelines Office Board, at the European Association of Urology.

Others present included representatives from both Permanent Missions, and the Universities of Belfast and Graz.

Speaking to media after the meeting, Byrne said: "There is currently a lot of optimism around personalised medicine, but plenty still remains to be done to turn the potential into reality."

"The importance of access to medicines and innovative treatments is undergoing particular scrutiny at the moment, and many stakeholders firmly believe that access for patients to medicines that efficiently treat illness is one of several important issues that must be addressed on a global scale," he added.

In the pipeline

- **3 October: SMART Outreach event in Warsaw, Poland**
- **6 October: Outreach in Belfast, N. Ireland**
- **8 October: EAPM oncology roundtable at ESMO Congress, Copenhagen, Denmark**
- **11 October: EAPM Access/Diagnostics roundtable during MedTech Week**
- **24 November: IVD regulatory workshop**
- **November-December: Outreach meetings in Italy, Germany and Portugal, plus Summer School webinar**
- **January-May 2017: Meetings in Spain, Romania, Germany and Italy, EAPM Annual conference, Outreach in Ireland and Portugal, plus Translational Research**
- **June-November 2017: Outeach events in Ireland, Italy, Spain, Portugal and Germany plus ESMO Congress, Madrid, and first EAPM Congress, Belfast**

SMART Outreach

Significant steps towards integrating personalised medicine into the Spanish healthcare system have been made at a key forum in **Madrid**.

The meeting, entitled "*Making Access to Personalised Medicine a Reality for Patients*", took place at Centro Nacional de Investigaciones Oncológicas under the umbrella of EAPM as part

of its SMART Outreach programme. SMART stands for Smaller Member states And Regions Together and the event aimed to form an informal network of stakeholders that can support an environment for personalised medicine at the national and regional level.

Among the conclusions of the event, hosted by Nuria Malats, were the fact that it is necessary to formulate a patient-centred strategy involving national decision-makers and regulators.

The meeting also identified the goal of enabling the EU and Member States to contribute to integrating personalised medicine into clinical practice while also enabling much-greater access for patients.

Speaking after the meeting Ms Malats said: "In order to provide a clear focus and to devote sufficient space to analysis, discussions during the conference concentrated on how Spain can contribute to this at the EU level and how this can be enhanced at the national level."

She added: "We met to assess and address obstacles to the integration of personalised medicine into Europe's healthcare systems, to identify best practices and their added value and to outline the potential benefits of personalised medicine on public health and its impact on policymaking in the EU."

"Now we need to go forward and support this action at the national level," she said.

During the meeting, Andalusia's Ramon Gonzalez Carvajal said that it is vital to highlight the role of the regions. "Because Spain is such a big country, the regions are important too, and this should not be forgotten," he told the event.

International research specialist Alfonso Beltran Garcia–Echaniz put forward examples of specific research instruments to foster personalised medicine in Health Research Institutes, and spoke about developing the European Strategic research and innovation agenda from a funding organisation perspective. He called for "research projects, a commitment to funding, and European coordination".

Patient advocate Natacha Bolanos, meanwhile, focussed on the difficulties inherent in assessing 'value' in modern medicine, pointing out that "patient ideas of value are often different from those of industry and health services".

And the Madrid Health Ministry's Teresa Chavarria Gimenez said that: "Patients want accurate diagnosis, access to treatments, symptom control and better information as well as true participation and empowerment."

She added that, for their part, "physicians need accurate pathology, prognosis and prediction, as well as access to technology and resources".

EAPM's executive director Denis Horgan said: "The Alliance is very supportive of such activities nationally, and this builds on all the work that EAPM has done at the EU level."

Several more SMART outreach events are coming up soon in Berlin, Krakow and Belfast (for dates, see the 'In the pipeline' box on Page One).

In **Sofia** during September the Alliance was part of a forum involving patient groups and the pharmaceutical industry, which agreed that access to medicines needs to be improved, although they partially disagree on exacty how best to achieve it.

The conference was organised by the Patient Access Partnership (PACT), a multi-stakeholder network, with a view to finding ways of improving access to medicines as well as the quality of care in Europe.

EAPM's executive director Denis Horgan spoke at the event, saying afterwards: "Getting all the important stakeholders in one room to discuss costs and access has always been something the Alliance has worked hard to do, again and again."

He added: "Only by getting these groups together can we make significant gains on the health of Europe's citizens."

PACT secretary-generall Stanimir Hasardzhiev acknowledged that major differences remain but he believes that the EU's

Member States are showing the political will to cooperate because no country can go it alone.

Meanwhile, in **Italy**, on 26 September, EAPM hosted a forum in the historical capital of the Emilia-Romagna region, Bologna (pictured above), and the full-day event saw a meeting of the Italian Alliance for Personalised Medicine (IAPM), which was launched in Milan earlier this year, followed by an EAPM annual general meeting to present an overview of activities and goals and to appoint new members to the board.

In consort with EAPM's 'Taking Stock' theme at the 2016 annual conference held in April, the new national Alliances will be analysing where stakeholders should go next relating to the implementation of the Council Conclusions on personalised medicine drawn up during the Luxembourg EU Presidency.

Giovanni Martinelli, MD, Hematology Professor, Institute of Hematology, said after the event: "Italy is a large country and it is important that we take into account the needs of individual regions as well as the nation as a whole."

Looking ahead to 2017

EAPM also already has much planned for 2017, including its annual conference (in association with the Maltese Presidency of the EU) and continued work in the reglatory area.

Also, from January-May 2017 there will be further Outreach meetings in Spain, Romania, Germany and Italy, plus further work on Translational Research.

Read more in our 'Forward Together' document, available here.

Other recent activities

EAPM played a role in a recent meeting hosted by the European Medicines Agency and the Alliance executive director Denis Horgan presented an overview of the regulatory direction of EAPM and highlighted the challenges facing Europe in that area.

Meanwhile, conference calls have recently taken place within the remits of the Alliance's Working Groups on Access and Healthcare Professionals.

Regulatory workshop

The Alliance will hold an IVD Regulatory Workshop later this year (24 November).

The title of the workshop is: ***Shifting Sands: Finding our way in the new regulatory terrain of In Vitro Diagnostics medical devices in Europe***.

Also planned (this time for 2017) is a high-level congress (venue to be decided), running over three days.

While much has been achieved through stakeholder interaction at the four EAPM conferences, with involvement from policymakers/regulators, MEPs, national healthcare officials, patient groups, HTA bodies, academics, researchers, healthcare professionals, industry representatives and more, the Alliance believes that the time has come to find practical on-the-ground ways to turn the dream of personalised medicine into reality.

This essentially means the practical integration of personalised medicine into Member State health care systems as swiftly and efficiently as possible. Clearly, at Member State level there are substantial differences and among those needing to be addressed are:

- Cross-border healthcare availability, especially in the smaller, often less-rich countries
- Wildly fluctuating costs of the same treatments and medicines
- Huge variations in reimbursement procedures
- A lack of agreement/consistency across Member State HTA bodies
- Cross-border collaboration in, for example, research (sharing knowledge and avoiding repetition)
- Interoperability issues
- Effective ways of gathering, storing and sharing Big Data
- Agreeing pan-EU best-practice guidelines

- Education for HCPs across all Member States

- Awareness raising of personalised medicine among the media and general public

All of the above are problems that require solving, quickly, if we are to see the right treatment for the right patient at the right time for every one of the EU's 500 million citizens regardless of where they live and their financial status.

The Congress will aim to address these issues.

In the news

As ever, EAPM has had articles published in the media recently. Readers can access these by clicking on the titles below.

Madrid event floats personalised medicine needs at national level

Europe to present personalised medicine goals at UN General Assembly

Who wants to live forever? How things have changed since Freddie died of Aids

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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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