



European Alliance for Personalised Medicine

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IVD regulations in the EAPM spotlight

Welcome to EAPM's November newsletter.

IVD Workshop

Later this month will see the Alliance hold a key workshop entitled '*Navigating our way in the new regulatory terrain of IVD medical devices in Europe*'.

The meeting will take place in Brussels on 24 November and will address several key topics.

These are set to include information about new regulatory processes, in particular the European Medicines Agency's interaction with other bodies and a request for guidance regarding newly defined processes.

Stakeholders will also discuss how developers will be able to ensure that IVD requirements are met in a timely manner, whether there will be supportive workshops and what the mechanism for feedback will be.

Also on the table will be an analysis of the EU's IVD Regulation in a global context. For example, how does it differ from, say, the US and Japan and are there any unique elements in Europe that are not mirrored at global level?

For the first time, devices manufactured and used only within health institutions established in the EU (in-house tests) will be regulated under the IVD Regulation.

In-house assays are allowed to be put into service under the Regulation where there is no equivalent CE-marked device on the market – this will need to be justified by the health institution.

Assays manufactured on 'an industrial scale' cannot benefit from the in-house exemption.

The Alliance has noted that there is no implementing act in the Regulation foreseen for in-house testing, and will therefore ask for some guidance.

There is also the question of how to find the right balance between supporting the development of essential in-house tests and fostering innovation on the one hand, and ensuring transparency and safety for patients on the other hand.

These and other IVD-related topics will come under the microscope at this month's workshop.

In the pipeline

- **24 November: IVD regulatory workshop**
- **November-December: Summer School webinar, follow up meeting on Access report with MEPs, plus Working Group meetings on Big Data, Regulatory Affairs, Access/Value and Education & Training of HCPs**
- **January-May 2017: Meetings in Spain, Romania, Germany and Italy, EAPM Annual conference, Outreach in Ireland and Portugal, plus Translational Research**
- **June-November 2017: Outreach events in Ireland, Italy, Spain, Portugal and Germany plus ESMO Congress, Madrid, and first EAPM Congress, Belfast**

ESMO Congress, Copenhagen

For the third year in succession, the Alliance held a high-level workshop alongside the annual ESMO Congress.

This year's congress of the European Society for Medical Oncology, a huge gathering of cancer experts, took place in Denmark and was arguably the most-successful ever.

According to Professor Andrés Cervantes, Scientific Chair of the event, the: "ESMO 2016 Congress has broken records, not only of attendance, but in terms of the quality science being presented, that will impact the practice of oncology."

Cervantes said that the key points emerging from congress were: "The accent on immunotherapy, that has changed the oncology landscape as well as targeted therapies and personalised medicine in general. The use of biomarkers for predicting response and outcomes is of huge benefit to patients."

The Alliance was present throughout the five-day event and



SMART

Smaller Member States And Regions Together

its own meeting went under the title *'Taking Stock – The role of science in oncology to realise a healthier world in the personalised medicine era'*.

The executive director of the Alliance, Denis Horgan, chaired the side-event, which began with Queens University Belfast's Mark Lawler speaking on the role of data in ensuring better access to treatments.

Prof Lawler was followed by Jill Walker, Executive Diagnostic Expert, Personalised Healthcare and Biomarkers, who spoke on the challenges of personalising treatment in oncology, specifically on drug development and implementation.

Later, Illumina's Rob Hastings covered the implementation of genomics into the healthcare system before Kings College London's Prof Gordon McVie (who is also EAPM's co-chair) explored the role of health literacy and communication.

A further topic heard during the meeting was the role of guidelines and education & training of healthcare professionals. This was covered by James N'Dow, Chairman of the Guidelines Office Board at the European Association of Urology and Ian Banks, of the European Men's Health Forum.

The final speaker, who spoke on the subject of Rare Cancer Advocacy: The voice of the patients, was Francesco De Lorenzo, President of the European Cancer Patient Coalition.

Also at the meeting, Ian Banks said: "There can be little doubt that the emergence of personalised medicine has now found its way into policymakers' mindsets, not to mention new stakeholders, most notably the patients.

"There's a long way to go but the journey has certainly begun."

SMART Outreach

In early October, the Alliance hosted a very different meeting inside a glass house facing the Brussels European Parliament.

'The transparent' gathering, held in the type of building

associated with sunshine and growth, was entitled *'The role of science to realise better access to healthcare'* and attracted much interest from passers-by, as well as a full house of delegates.

Around 50 attendees from a broad-base of stakeholder groups filled the temporary glass house on the European Parliament Esplanade, during the event that took place on 11 October.

Three MEPs (Marian Harkin, Lambert Van Nistelrooy and Cristian Busoi) addressed the high-level meeting, which also saw speakers drawn from AstraZeneca, Intel, the European Patients Forum, genetic giants Illumina and Roche.

Lambert Van Nistelrooy, who spoke on the topic of regions and healthcare: reaching a balance said: "Many people will tell you about the disparities and inequalities in access to personalised medicine between different EU Member States.

"This is a large part of the problem, yes, but there are also sometimes huge differences between regions in individual countries.

"We need to do a lot of work in this regard and EAPM, with its **SMART Outreach programme**, is getting out-and-about and on-the-ground to try and solve the many problems where they are occurring."

Romania - SMART and TEACH

A few days later (19 October) the Alliance played a key role in a cutting-edge conference in the eastern-European city of Bucharest.

The gathering followed in the wake of an earlier satellite symposium held yesterday in the Romanian capital, also addressed by EAPM.

At the conference in Cotroceni Palace, a key topic was access to, and shortage of, medicines, which is in the news at the moment due to a scandal on the 'unethical' over-pricing of cancer drugs in Italy.



This saw a pharmaceutical company, Aspen Pharma, fined €5.2m last Friday for abusing its dominant position in the cancer-medicine market, and effectively blackmailing the Italian regulatory agency over prices that it attempted to boost by up to 1500%.

The scandal has seen pressure groups and consumer watchdogs ramp-up calls for the European Commission to launch a probe into medicine shortages.

The purpose of this would be to examine whether these shortages are being used as a tactic to up prices charged to Member State health authorities.

At the Bucharest conference EAPM's executive director Denis Horgan was joined by Diana Păun, Health Advisor at the Romanian Presidency; Marius Geantă, President, Center for Innovation in Medicine, and MEP Cristian Bușoi in the early addresses. Many other speakers shared the floor.

A multi-dimensional debate took place covering topics such as investment and the role of education in training healthcare professionals in order that they come up-to-speed with today's fast-moving developments in genetics, data and more.

Horgan said 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-general 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, Bucharest will also see EAPM host its second, week-long school for young healthcare professionals, or HCPs.

Building on the success of the inaugural Summer School in Cascais, Portugal, the concept will be taken east, from 3-7 July next year.

The school is entitled 'TEACH', which stands for **Training and Education for Advanced Clinicians and HCPs**, and the goal is to bring young HCPs up-to-date with developments in this exciting field.

Aimed at young healthcare professionals aged 28-40, TEACH works on the basis that, if personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high-quality healthcare, then clearly it must be made available to many more citizens than it is now.

The school dovetails with EAPM's call on the Commission to focus funds to stimulate a Continuous Education and Training Programme for HCPs in the context of personalised medicine.

Why Bucharest?

The barriers to integrating personalised medicine into healthcare systems often loom larger in the EU's eastern Member States, due to several reasons including the fact that they tend to have less resources than their counterparts and many of their healthcare professionals migrate westwards.

The choice of Bucharest (pictured) as the 2017 venue also ties-in well with EAPM's SMART Outreach project. SMART stands for **S**mall(er) **M**ember states **A**nd **R**egions **T**ogether, and the Alliance has been expanding this by taking its message directly to EU countries.

The role of Belfast, Northern Ireland

The Alliance recently held a key meeting in **Belfast** to introduce areas being addressed at EU level in a way that could be integrated into the healthcare system at national level.



A key objective was to design a roadmap for engagement linking Northern Ireland and other 'regional' stakeholders.

The high-level gathering also saw the official announcement of a major new congress to be held in Belfast (pictured) in around a year's time (November 2017), also organised by the Alliance. More details will follow in due course.

In the news

As ever, EAPM has been busy in the media. Click the links below to read our more recent articles.

[Italy drug scandal highlights access to medicines issues](#)

[Deafening silence on health care in presidential debates](#)

[Bucharest hosts key conference on personalised medicine](#)

[Balancing societal needs and legislation in modern-day health care](#)

[Transparent alliance lets light shine on personalised medicine](#)

[DataSharing: Let's build on foundation of #PersonalisedMedicine](#)

[EAPM announces major 2017 Congress](#)

[No place for poor science in personalised medicine](#)

[Hype v Hope – Why PM doesn't hold all the answers...yet](#)

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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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