



European Alliance for Personalised Medicine

EAPM Bulletin: Issue 27, June 2017

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Hot weather, but EU health is still in hot water

Welcome to our June newsletter. Summer is well on the way but, hot weather or not, we're still busy here at EAPM.

Two very successful meetings were held last month in Milan on patient empowerment and lung-cancer screening and, of course, our second Summer School for healthcare professionals comes up this month in Bucharest.

On patient empowerment, the key goal of the high-level gathering was to align efforts internationally via a central focus to agree one policy, backed by multi-stakeholders, to put in front of policy-makers.

The event was organized by the Università degli Studi di Milano, in co-operation with the Fondazioni Umberto Veronesi.

Organisations at the Forum included the European Cancer Patient Coalition, European Alliance for Personalised Medicine, the European Society of Medical Oncology, and the European Organization for the Research and Treatment of Cancer.

"A central aim is to remind the EU and its Member States of the EPAAC and CanCon initiatives and call on the EU and Member States to collaborate," said EAPM co-chair and former European commissioner for health David Byrne, who addressed the meeting.

"There is a need in the fast-moving area of healthcare for a focus on preventative care and personalised health care. This is something the Alliance has always been geared towards and this meeting in Milan can only help to further our goals and those of our fellow stakeholders," he added.

The lung-cancer screening meeting, meanwhile, came in the wake of EAPM's fifth annual conference, which tackled the topic, and the Alliance's presence in Italy was also an example of its stated commitment to help to bring alignment between EU activities and the national levels, as well as between Member States.

This EAPM policy and priority exemplifies its SMART Outreach approach. SMART stands for Smaller Member states And Regions Together and has seen the Alliance hold high-level meetings in several EU countries.

The forum built on a conference held last year, in the same city, that focused on making access to personalised medicine a reality for patients.

The cornerstone of the event was to align efforts

In the pipeline

- **22 June: EHA Round Table Meeting "EU options for improving access to medicines," Madrid, Spain**
- **26 June: Smart Outreach Meeting, Bucharest**
- **27-30 June: Summer School, Bucharest**
- **10 Sept: ESMO/EAPM roundtable, Madrid**
- **27-30 November: EAPM Congress, Belfast**

internationally via a central focus geared towards empowering Europe's patients and introducing guidelines for lung-cancer screening.

DG Justice calls for applications

DG Justice is seeking applicants for a GDPR expert working group. It will be important to have representation from our sector here, so please do consider applying and please share with your contacts.

Full details can be found under 02/06/2017 at the Register of Expert Working Groups.

This is an issue that the Working Group on Regulatory Affairs will be following on a regular basis, including through the SMART Outreach programme, and it was brought up by stakeholders in the patient empowerment event in Milan.

The topic will also be discussed with politicians in Bucharest (prior to the Summer School) on 26 June.

Access

Access to medicines is sure to be a priority at the World Health Organization throughout 2018.

Unfortunately, supporters of a UN report on drug prices



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and intellectual property feel that current Director General Margaret Chan (she is replaced on 1 July) ignored a push to make the report a stand-alone item in WHO discussions.

This is an issue that EAPM's Working Group on Access and Value will be following on a regular basis. Meanwhile, the Alliance is organising a meeting with ESMO to discuss this. Our engagement with politicians continues on a regular basis, and access will be a key focus of our second meeting in New York in September, alongside the United Nations General Assembly.

Council and the proportionality directive

The Competitiveness Council has backed a Commission plan for rules to check if new restrictions by EU countries on regulated professions, such as doctors and nurses, are proportional.

The Commission wants to ensure that Member States don't introduce unnecessary rules that could restrict professionals moving from one EU country to another in order to practice.

This is a key topic in EAPM's Education and Training of HCPs Working Group, and will also be an item of discussion at the Summer School.

Upgrading and upskilling are key challenges that the Alliance recognises need to be overcome in order that personalised medicine can be integrated into healthcare systems.

Blood and tissues

The Commission wants opinions on whether its 2002 directive setting quality standards for human blood, as well as a 2004 directive on human tissues and cells, remain effective.

The deadline for us to have our say is 21 August.

This will be an item for discussion at the EHA roundtable (which we are organising with the haematology community on 22 June), entitled *EU options for improving access to medicines*.

Frustration over failed pricing deal

Being a current and future topic at our Working Group meetings, as we aim to close the HTA discussion at Commission level, we noted that Belgium and the Netherlands have failed to get a pricing agreement in their first joint negotiation on a medication, the cystic fibrosis drug Orkambi.

The two countries did not manage to get what they thought was an acceptable price from makers Vertex in what was their first public announcement since they began collaborating on prices, back in 2015, for drugs used to treat rare diseases.

Belgium's INAMI Drug Reimbursement Commission and the Dutch Health Care Institute said: "Both institutes consider that the product is not cost-effective".

Belgian Health Minister Maggie De Block, who spoke at our fifth annual conference, appeared disappointed, saying that she expected Vertex to make Belgium and the Netherlands an "acceptable offer," adding that "we cannot commit a large part of the budget for a single drug".

The drug's official price in Ireland was €159,000 per patient per year at the end of 2016. Negotiations have ended for now.

Live seminar for oncologists

The open access education platform for oncologists, ecancer.org, is hosting a live seminar direct from the ASCO 2017 Annual General Meeting on 5 June, which will discuss the latest trial results for prostate cancer treatment.

The speakers are Neal Shore, Kurt Miller, Karim Fizazi and Nick James. You can register your place now, [here](#).

Post-Brexit criteria for agencies released

The European Commission has released the criteria for hosting the EMA, which is currently London based, after Brexit. Also up for grabs is the European Banking Authority.



Donald Tusk, the European Council president, and Jean-Claude Juncker, the president of the European Commission, have made it clear that minimising the disruption of services is “vital” and that the city finally chosen must ensure “business continuity” as the UK leaves the EU.

Almost every EU Member State has applied to host one of the two agencies, with some entering both ‘competitions’. Copenhagen, Amsterdam, Milan, Stockholm, Barcelona and Dublin are all bidding for the EMA and more applicants are expected by the 31 July deadline.

The agency employs 900 qualified professionals and is a hub for pharmaceutical experts.

TEACH Summer School

Following on from last year’s success, a second Summer School for healthcare professionals will be taken east to Bucharest, Romania, and run from 27-30 June.

As it was in 2016, the school will be entitled ‘TEACH’, which stands for Training and Education for Advanced Clinicians and HCPs, and the goal is to bring young, front-line professionals up-to-speed with fast-moving developments in the field.

Aimed at age-range 28-40, TEACH holds to the thesis that equal access to high-quality healthcare must be made available to many more citizens than is currently the case.

Belfast Congress

During the coming months, EAPM will be focusing on and developing the policy asks that will be set out in this First Annual European Personalised Medicine Congress, to be held across four days (27-30 November) in Belfast, Northern Ireland.

The Congress website, the abstracts portal, and online [registration](#) have been launched and the current programme is available to view [here](#)

Key areas that the Congress will focus on include:

• **Patients**

Modern-day patients are better informed than ever before and are demanding to share in co-decision-making about issues affecting their treatments. They are also hugely in favour of being able to share their own private health data (under strict ethical and privacy provisions) for the benefit of fellow patients and future generations.

• **Education & Training**

Healthcare professionals (HCPs) are falling behind with front-line knowledge as developments in personalised medicine move swiftly. Europe must put programmes in place to bring, and keep, these HCPs up to speed, while improving their interaction skills with patients.

• **Regulation**

Proponents of personalised medicine believe that much legislation governing aspects of healthcare is out-of-date and not fit for purpose in these fast-changing times.

Despite health largely remaining a Member State competence, regulations and directives must be brought to modern levels through a consensus of experts and key actors, including patients.

• **Research & Development**

EAPM has always promoted state-of-the-art research, and this will be a focus of the Belfast Congress.

The Congress, to be held at The Waterfront venue (pictured on page 4), will see 35 parallel sessions plus ten presidential sessions during the week.

Here is a further link that readers should be aware of: to submit abstracts, click [here](#)



In the news

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

[#EAPM: Alienation will only add to woes of Europe's patients](#)

[#EAPM: Genetics, empowerment, and doner kebabs...](#)

[#EAPM: DG SANTE – A force for good for Europe's citizens](#)

[#EAPM: Register now for the Summer School for HCPs in Bucharest](#)

[#EAPM: Commission steps up health-care data strategy](#)

[#EAPM: Empowerment for patients is way of the future](#)

[European Association of Urology and #EAPM to move to put prostate cancer high on the agenda](#)

[#EAPM: Lung cancer screening debate moves to Milan in mid-May](#)

[#EAPM: #Macron to be congratulated but where now for French health care?](#)

[#EAPM: MEPs urge Commission to ramp up Big Data initiatives in health care](#)

[#EAPM: The need for early advice \(and more\) on novel medicines and treatments](#)



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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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