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## A very warm welcome to Belfast Waterfront

Welcome to the opening day of EAPM's first Congress on '*Personalising Your Health: A Global Imperative*' here in Belfast, Northern Ireland.

This is the first of five daily newsletters which, across the week, will be highlighting what has happened already and what is to come later in the day. Attendees will receive them electronically.

Earlier today, EAPM executive director Denis Horgan opened the inaugural Congress.

As part of his welcome address, he said: "Most of you will know that the European Alliance for Personalised Medicine brings together extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics.

"This involves patient groups, academia, health professionals and industry, while we also engage in ongoing dialogue with the European Commission, Parliament and the EMA.

"I'm delighted to see that representatives from all of these areas are with us this week."

Denis spoke about the ongoing, multi-layered policy goals of the Alliance, saying: "A founding and ongoing principle of EAPM was, and is, to bring together all stakeholders to create a one-stop-shop allowing us to find consensus where possible and also allowing us to speak in a constructive language that regulators and institutions understand.

"EAPM will continue to do this and, over five years, has achieved many successes through such methodologies, not least through our five annual conferences. Four of those were held in Brussels, but the first was held in Dublin.

"Happily for this, our first Congress, we decided to come back to the Emerald Isle, albeit the northern part, because as Brexit looms large we believe it is important to emphasise the close relationship that the European Union has with people in Great Britain and Northern Ireland, essentially the UK as a whole.

"2021 will see the centenary of the Anglo-Irish Treaty and, although Great Britain, Northern Ireland and the South have seen some difficult times, citizens have been able to move forward within a constructive relationship, reflected in our common visions."

### Today's highlights at a glance

- Capturing the Global Picture in Precision Medicine
- The Value of Sustainable Healthcare
- Presidential session: Shaping Future Healthcare Systems and the One Health Agenda
- Special lecture: Alexander Eggermont, Director General, Institute Gustave Roussy, Paris, France
- Welcome reception at Belfast City Hall: Featuring awards for Patient-centric Innovator and Smaller Member states And Regions Together (SMART)





Simon Harris, Minister of Health, Republic of Ireland, speaking at the opening of Congress. Photo by Simon Pugh Photography

Denis continued: "This agreement was set out in three strands which covered a complex series of provisions relating to a number of areas.

"These included: The status and system of government of Northern Ireland within the United Kingdom; The relationship between Northern Ireland and the Republic of Ireland, and; The relationship between the Republic of Ireland and the United Kingdom.

"It was a landmark accord that must be retained in full despite Brexit, and I'm sure all of us in this room look forward to a similarly constructive relationship continuing between Great Britain, Northern Ireland, the South and the EU as a whole, especially in the arena of health in general and personalised medicine in particular."

The EAPM executive director added: "Personalised medicine puts the patient at the centre of his or her own healthcare. It aims to offer the right treatment to the right patient at the right time. And, crucially, it is for the many and not the few.

"Personalised medicine is not designed to become a high-tech concept available solely to the elites.

"Unfortunately, at the moment, equitable access for all patients to the best treatment available, regardless of their location or income, does not exist. There are too many price issues and discrepancies, for a start, and we evidently need to find new ways to reward innovation while bringing down costs.

"Going forward, we need to ensure that our systems are adaptable enough to facilitate this vital innovation. This clearly means that the traditional way of delivering healthcare needs to change, as it doesn't work in the 21st century."

"We all have a part to play in developing the role and scope of personalised medicine. And it has to be said that before the vision of personalised medicine can become a reality, industry, scientists and regulators will have to cope with the challenges they face by being imaginative, by moving away from silo thinking and by solving problems together," Denis said.

Speaking in the same session, MEP Cristian Busoi MEP explained reasons for the Congress. He said: "Action is necessary at a cooperative and EU level - in gaining new insights into diseases, personalised medicine is already becoming the dominant therapy for cancer and a host of other afflictions.

"Quality assurance needs to be further developed to respond to patients requirements. And affordability is the most crucial issue - can we 'afford' to beat cancer?"

#### **Presidential Session: Growth in personalised medicine - The promise for future generations**

Earlier today, the first session discussed various weighty issues. Concerning the regulation of medicines in the EU, which is an integral part of personalised medicine, Dublin's Health Products Regulatory Authority Chief Executive Lorraine Nolan said: "I think we have a really good reputation in terms of regulations of medicines within the EU. We're viewed as open and progressive. Tough, but fair.

"Much has changed in the regulatory mindset - regulators are working to ensure that they stay abreast of the latest innovations.

This was a theme that was expanded on by European Organisation for Research and Treatment of Cancer Director General Denis Lacombe, who was in Belfast from Brussels: "New regulations should therefore be good news. The European Commission has adopted a directive in order to pave the way for a pan-European research area. The principle is fine, the implementation is the problem."

Mark Lawler, chairman in Translational Cancer Genomics, Queen's University Belfast said: "We must look at how to realise the promise of the patient-centred approach. Better methods of treatment and treatment education need to help the person at the level of the person."

Desmond Schatz MD, of the UF Diabetes Institute said: "There is a sense of urgency and a call for action on diabetes

# Personalised medicine: the writing's on the wall

Top: Cristian Busoi; centre (left to right) Mueen Sharaf, Sebastian Schmidt; bottom Mark Lawler, Ivana Cattaneo & Emanuele Ostuni.  
Photos by Simon Pugh Photography





# European Alliance for Personalised Medicine

- understanding the disease is key to personalised medicine treating it.

"Diabetes is the epidemic of the 21st century - at present, there are 415 million sufferers, with 620m projected by 2040. Treatment requirements are not being met by current methods."

And Peter Meeus, who is head of Region Europe, Shire, London concluded on diabetes: "With 415 million people living with the condition globally, and costing health-care systems about \$465bn annually, it's no surprise that much of the healthcare world has its eyes on diabetes and the damaging effect it can have both economically and to the individuals who live with it."

## **European Hematology Association Session – Personalising treatment of blood diseases – Taking advantage of the leukemia/lymphoma genome**

Earlier, the European Hematology Association session focused on the personalisation of the treatment of blood diseases.

In this context, the personalisation of hematology in general was covered together with the hematology research road map developed by EHA.

In addition, the session discussed the IMI2 HARMONY project which tries to integrate clinical data, informatics and research into the diagnostic and therapeutic algorithm of patients with hematologic diseases.

Many of the diseases in the hematology area fall under the definition of a rare disease. Personalisation, in particular with the new treatments available will cause a considerable financial burden on health systems. Therefore, the political dimension of access to innovative medicines is one of the topics.

## **Coming up later today**

### **Presidential Session – Shaping Future Healthcare and the One Health Agenda**

Trying to bring innovation into healthcare systems by dealing with just the fragments of the problem runs into challenges. The barriers to market access are not individual problems. They are the sum of all the individual problems. And the only way to tackle that is by addressing the system as a whole.

It's not enough to see bringing innovation to the market as a linear process.

For many healthcare innovations, the classic process just doesn't apply. It's no longer a phased exercise that leads from research and development to regulatory approval, and then to

health technology assessment and on to the final reimbursement decision.

Congress will hear that the inherent uncertainties of innovation demand more agile pathways that can take into account the evolving knowledge of a product's characteristics. Otherwise the promise of the innovation may not be realised at all.

Much of healthcare innovation now turns on identifying therapeutic targets and the use of paired diagnostic companions with novel molecules. The resulting optimisation of care, the increased efficiency and decrease in adverse events, and the reduced cost and waste resulting from more selective and rapid clinical studies are all welcome.

In other words, detailed adjustment of one or another parameter – such as a budgetary cap, or conditional marketing authorisation conditions, or additional opportunities for early dialogue with HTA bodies – are not going to suffice. It's a change in the concept of coping with healthcare innovation that is needed, a recognition that to solve the individual issues, an approach must be found to embrace the challenge of innovation as a whole.

The approach has to be not only more holistic, but also able to operate at a different pace. New technologies must be allowed access to healthcare systems at a faster rate than is the current norm. Otherwise they will perish.

This is not a bid for unconditional and imprudent anarchy. EAPM is not in favour of any "race to the bottom" or general erosion of standards – and it views with concern the proposals of US President Trump that threaten to take the FDA in that direction. But it is an argument for a realistic approach to the issues of safety and efficacy.

Across Europe's complex landscape for healthcare regulation, the responses so far have been fragmented, and at European Union level they remain administrative or technical rather than political.

Greater engagement at political level will be necessary in Europe to ensure the framework is conducive to innovation – and not just to today's innovation, but to the innovations that will emerge in the coming decade.

### **Special lecture: Alexander Eggermont, Director General, Institute Gustave Roussy, France**

We are delighted that Alexander, who is an EAPM board member, will give a special lecture today.

The Director-General of the Gustave Roussy Institute, a top cancer institute in Europe, he will talk about the revamping of

# Quotes from Congress



"Tapping into knowledge repositories to make full use of it for the benefit of patients is mainly a question of architecture. We need interoperable eHealth systems to gather, filter, analyse, and use Europe's health data, in full respect of patients' consent."

*Vytenis Andriukaitis,  
European Commissioner for Health and Food Safety*



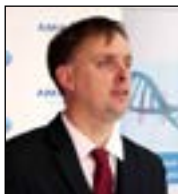
"There has been an issue between the pharmaceutical industry and Member States when it comes to the pricing of medicines. The Member States' buyers need to come together so that real progress can be made on pricing policy."

*Chris Fearne  
Minister for Health, Malta*



"Our most significant milestone has been the overhaul of our infrastructure to better reflect and adapt to the paradigm shift that is occurring in clinical research."

*Alexander Eggermont, Director General,  
Institute Gustave Roussy, Paris, France*



"It is clear that we need to engage in respect of personalised medicine at all political levels. The Alliance will do this in its role as a platform for all stakeholders in the arena of personalised medicine."

*Denis Horgan,  
EAPM Executive Director*

## A message from Vytenis Andriukaitis European Commissioner for Health and Food Safety

Whilst we have many similarities in our DNA, there are considerable genetic variations that make each one of us unique. With today's technological advances, it is fast becoming a global imperative to ensure that medicines are tailored to our specific physiology and needs.

As a medical doctor, I am convinced that personalised medicine holds huge potential for patients, offering better targeted treatment, avoiding medical errors, and reducing adverse reactions to medicines. More research is needed for its successful uptake in our health systems, and a key element in making this happen is to maximise the possibilities of big data in health 1.

Big data has enormous potential to advance medical research, bring about greater innovation in healthcare, and improve the overall performance of health systems. However, there are a number of barriers to fully capturing and making full use of the considerable health data we have in the EU, notably fragmentation of data sets and insufficient computing infrastructure to connect Europe's eHealth systems.

We are working together at the EU level to remove these obstacles so that we can help get innovative medicines to patients faster and improve our health systems.

Tapping into knowledge repositories to make full use of it for the benefit of patients is mainly a question of architecture. We need interoperable eHealth systems to gather, filter, analyse, and use Europe's health data, in full respect of patients' consent.



Deputy Prime Minister of Malta Christopher Fearné addresses delegates at the Waterfront venue in Belfast. Photo Simon Pugh Photography

their clinical research infrastructure to adapt to the rising new field of translational research and his ambitious plans for the next five years, in particular, his vision for Cancer Core Europe, positioned to be a virtual European Cancer Institute.

Gustave Roussy is a comprehensive cancer centre, which means it works in the three areas of care, research, and education. It is the largest cancer institute in Europe by volume of activity; seeing up to 12,000 newly diagnosed patients a year.

The institute can be seen as the European counterpart of the Memorial Sloan Kettering cancer center in the US.

Alexander will say that he can "attribute this success to the major changes we have implemented during the past five years".

"Our most significant milestone has been the overhaul of our infrastructure to better reflect and adapt to the paradigm shift that is occurring in clinical research."

Previously, he will tell Congress, the fields of basic and commercial research were fairly separate, but a rising new field called 'translational research' is transforming the landscape, with new developments like molecular diagnostics and immunotherapeutics.

Previously in clinical research, phase I trials were used to identify dosage-toxicity relationship, phase II to determine response rates and phase III to evaluate the efficacy of the drug in randomised controlled trials.

Now, phase I studies are complex biomedical programmes that can only be executed if the research environment and laboratory infrastructure provide all the necessary resources required., he will add.

### **EAPM 2017 Welcome reception**

The Welcome reception will take place tonight at Belfast City Hall. Located In the heart of the city centre, at Donegal Square, the Hall is one of Belfast's most iconic buildings.

It first opened its doors doors in August 1906 and is Belfast's civic building.

Chloe Smith will speak at City Hall. She is Conservative Member of Parliament for Norwich North and is Parliamentary Under-Secretary of State for Northern Ireland.

As well as the speech, the reception will feature two EAPM special awards, for the 'Patient-centric Innovator Award' and the SMART award, which stands for Smaller Member states And Regions Together.

The first recognises achievements by a member of industry that focuses on putting the patient at the centre of his-or-her own care, while the second recognises a Member State or region that has contributed greatly to the development of personalised medicine.

### **Notes on the Estonian Presidency of the EU**

It isn't just hype. After a slow start in much of Europe, the advent of digital technology really is transforming healthcare – and, more to the point, is going to transform it even further in the coming decade.

Look at the miracle of computerised tomography, and the still greater miracle of how transmitting it over the internet from radiology centres can put detailed patient information in front of a treating physician even in another hospital.

A great leap forward. But greater leaps are to come. Right now it takes about a quarter-of-an hour to download that CT image – but by 2025, faster networks could cut this to under a minute.

And the download time for human genome sequencing – with the unparalleled knowledge about individual patients this has provided to medical research – could be slashed from the current one month to little more than a day.

No-one knows better than Estonia the merits of putting the digital society at the service of health. Over the last ten years it has revolutionised its healthcare system with e-solutions for the entire population, offering doctors, patients, hospitals and the



Gennaro Ciliberto. Photo by Simon Pugh Photography



government new levels of convenience, access and savings.

Electronic health records, combining data from Estonia's 800 healthcare providers, create for each patient a birth-to-death medical history, and feed into the electronic health registry that gives doctors nationwide access to critical information, and compiles data for national health policy decisions.

A linked e-prescription system cuts down on paperwork and doctor visits and simplifies administration of reimbursement. And based on its domestic experience Estonia is helping pioneer advances at EU level too in putting technology to work in healthcare. EAPM is delighted to be working with the presidency.

### ***Our friends in the European Parliament***

MEPs Marian Harkin and Cristian Busoi will be representing the European Parliament here this week.

European politics are always evolving, and politicians, in the European Parliament and elsewhere, have to adapt to that evolution. But the rise of participatory democracy has presented Europe's politicians with an entirely new challenge.

The readiness of so many of today's citizens to articulate their own policy ambitions, coupled with the availability of increasingly influential new channels of communication, has radically changed the context within which policy discussion and policy formation take place.

Said Busoi: "At its best, this can offer the political class the opportunity of a new and vibrant interaction with the electorate. But it can also result in an awkward myriad of competing and even conflicting demands for action."

Politicians at the EU level are today confronted with a complex patchwork of interests and claims for attention, and frequently find themselves with real difficulties in reconciling them.

The current political scene is characterised by a high degree of public disenchantment and distrust, because of the unprecedented mis-match between citizens' multiple aspirations and expectations, and what they perceive – or occasionally misperceive – that politicians have delivered.

The EU itself is a prime example of a victim of such public misunderstanding: it is widely criticised for what are seen as its failings (even when the problems laid at its door are often the consequence of unrelated factors at international, national or regional level), but it receives little credit for its successes.

Busoi added: "An obvious question arises as to how that gulf may be bridged. And like all successful bridges, the span needs to be firmly anchored on each side.

"So politicians need to find more effective ways of reaching out to and connecting with voters."



EAPM's Denis Horgan addresses delegates. Photo by Simon Pugh Photography



Irish MEP Marian Harkin joined speakers and delegates at Congress this morning. Photo Simon Pugh Photography

## """"""""""Quotes from Congress""""""""""



**"There is a sense of urgency and a call for action on diabetes - understanding the disease is key to personalised medicine treating it."**

*Desmond Schatz MD  
University of Florida Diabetes Institute*



**"We must look at how to realise the promise of the patient-centred approach. Better methods of treatment and treatment education need to help the person at the level of the person."**

*Mark Lawler  
Queen's University Belfast*



**"Technology advancements do not know borders, so countries must work together, share knowledge and experience."**

*Simon Harris  
Minister of Health, Republic of Ireland*



**"It is important to highlight that personalised medicine will have to become available to all, and not just to the privileged elite."**

*Marian Harkin  
MEP*



# Belfast: Painting pictures of our host city



All photos by Simon Pugh Photography



Twitter hashtag for this Congress:  
[@eapm2017](https://twitter.com/eapm2017)



European Alliance for  
Personalised Medicine

*In close collaboration  
with our partners:*



Estonian Presidency  
of the Council of the  
European Union



**Platinum partners:**



**Gold partners:**



**Silver partners:**



**Bronze partners:**



**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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