CONGRESS REPORT

EAPM 3rd Annual Congress:
‘Forward together with innovation: The importance of policy making in the era of personalised medicine'  

3-4 December, 2019
University Foundation, Brussels
Innovation
translation of knowledge and insight to value for benefit of citizens

Value
Value to individuals - citizens/patients, society and healthcare community.

PUTTING THE PERSON INTO PERSONALISED MEDICINE
CONGRESS REPORT

'Thank you!' from EAPM

Welcome to EAPM's Third Annual Congress report, a review of our event which took place at the Fondation Universitaire in Brussels.

The Alliance would like to take this opportunity to thank all those who spoke, attended and helped to organise yet another successful event as we work our way towards 2020.

Prior to Congress, it had already been a busy year, dominated by the Parliamentary elections, the setting up of a new Commission under Ursula von der Leyen, a review of the Orphan Regulation, wrangling over mandatory aspects of HTA and Brexit.

Our two previous Congresses were held in Belfast and Milan, but the reasons we chose Brussels for 2019 are alluded to above.

The truly awesome stuff in personalised medicine is happening on the ground. Not as quickly as the majority of us would like, of course. But it is undeniably happening. What once seemed opportunities for the future are with us here, right now, today. These opportunities are ready to be grasped and moulded into realities.

Our Congress once again reflected that.

It was held under the auspices of the Finnish Presidency, and titled “Forward together with innovation: The importance of policy making in the era of personalised medicine.”

As ever, Congress showcased different objectives which both the public and private sector can support, with a view to allowing the EU to present a common objective. It took place in a focused format to allow concrete issues to be tackled and to have a dialogue with our policymakers.

Personalised medicine is becoming more-and-more mainstream, but we’ve still a long way to go. The opening session on Day One of the event covered facilitating an environment for delivery of better healthcare for the EU and Member States.

This was followed by sessions on Big Data and healthcare, public health, translational research and bringing innovation into healthcare systems.

Day Two featured sessions on the current hot topic of the Orphan regulation, evidence frameworks, plus value-based outcomes and biomarkers. Biomarkers were also discussed, on the back of a pre-Congress roundtable on the subject, in connection with molecular diagnostics.

Much more was on the table in Brussels, and we hope that this report gives you a flavour of the event which aimed to examine all pertinent scenarios, ask the right questions, and endeavour to come up with answers that allow us, in practical and value-based terms, to move forward together.

Many Members of the European Parliament, who have a keen interest in healthcare in general and personalised medicine in particular, were with us at the event.

Down the decades the competences and influences of the EU’s only directly elected body has grown, with a great leap (8%+) in turnout figures for the elections earlier this year.

For some time, Parliament has worked to improve the health and access to better outcomes for all citizens in every Member State.

Across the years, and more-and-more in recent times, the European Parliament in concert with the European Commission and Member States has managed to introduce, or is currently finessing, legislation on Orphan drugs, cross-border healthcare, clinical trials, in vitro (and other) medical diagnostics, health data, health technology assessment and more, that has a broad and beneficial impact on health and welfare for all.

Progress has certainly been made, but many challenges remain. Not least regarding the question of how we harness the immense power of big data, not least in healthcare, for the benefit of our citizens, while at the same time behaving ethically and protecting their privacy.

As ever, balances are required, compromises made. But all stakeholders are part of a cohort that is always striving to move ‘forward as one’.

David Byrne, co-chair EAPM
Gordon McVie, co-chair EAPM
Denis Horgan, executive director, EAPM
What happened at Congress...

Our third annual Congress took place from 3-4 December, beginning at 15.00 on Tuesday, 3rd.

Ahead of the Congress opening, EAPM held a pre-meeting on exploring how patient access to biomarker testing can be improved.

The event covered such important issues as the role of biomarkers in the diagnosis of cancer, testing for biomarkers (including rates of testing, speed of results and reliability/accuracy) and availability of related therapies.

Also up for discussion was the current limitations of biomarker-testing practices, the potential use of centralised databases, and advice that is, or should be, given to patients linked to biomarker testing.

These topics were placed against a background of expected developments in the field of testing over the next five years.

Day One

Facilitating an environment for delivery of better healthcare for the EU and Member States

Gordon McVie, co-chair EAPM, welcomed attendees and reminded them that “Eight years ago, we set up the alliance with patient groups, and it is getting better and better. It’s very important that patients are still here with us, because whatever we do, it has to impact patients.”

Denis Horgan, executive director of EAPM, took up the theme, saying: “We are a multi-stakeholder organisation bringing together patients organisation, as Gordon said, in different disease fields.

“The idea was and is to put the patients at the centre of their own healthcare, and we wanted a more inclusive voice to draw recommendations to policymakers for the improvement of policy to access personalised medicine.

“Research, industry, education, patients...we bring together stakeholders to identify the challenges and problems, exploring policy regulation and recommendations.

“How do we improve the quality of life of a patients, improve access to diagnostic and treatment? How do we improve quality of life to the implementation of personalised medicine?” Denis asked.

“We provide a framework for action, inviting the Commission, Member States, MEPs, to focus on big data, education and training of healthcare professionals, mutualisation of data, avoiding duplication of research in Europe...removing the barriers to access to personalised medicine.”

Denis explained that another key area is genomics and access to data. How do we protect and empower the data in the fields of research and healthcare? What about the issue of consent?

We came up with the MEGA+ initiative where sequencing is not the objective, but rather to mutualise the data. With the support of the European Commission and Member States there will be a CSA to support this activity.

Big Data and healthcare

On the topic of Big Data and healthcare, Marco Marsella, Head of Unit eHealth, Wellbeing and Ageing, at the Commission, said that data will help to implement personalised medicine.

A massive quantity of data is coming, Marco said, explaining that at DG Connect there is a strategy to bring innovation into the healthcare system.
This includes:

- Access, integration, communication of health data
- Cross-linking datasets
- Interoperability data/systems/technologies
- Cybersecurity and Data Protection (RGPD that gives the right to consent)
- Innovative solutions for prevention, diagnosis, treatment, care
- Artificial Intelligence, clinical decision support systems
- HPC, blockchain, big data analytics, the Internet of Thins, cloud computing

Marco (above) explained that, in February 2019, The European Commission adopted a Recommendation on a European Electronic Health Record exchange format to improve access to data across borders.

This sought to allow interoperability to ensure that data are understood and treated the same way across borders. This is a good place to start, he said.

He added that the Commission also pushed forward with work to support the infrastructure within Member States. For example, Estonia and Finland have already produced the first 5,000 prescription exchanges, and more are coming.

Regarding the declaration of cooperation on genomics, Marco spoke about working groups that have been set up and the beginning of cross-border exchanges.

“Now not only will we share data, but we will transfer algorithms” he said, adding that “this is one of the new challenges that goes beyond data sharing. We are making progress in defining the procedure”.

In addition to policy framework support, the digital transformation of health is also aided by, among other things:

- Increased investment in the field of research (more than €1 billion investment)
- ICT solutions for prevention, diagnosis, treatment and care
- Big Data, AI and robotics, smart systems and wearables
- Around €80 million for eHealth deployment and interoperability
- Cross-border health services, including patient summary, ePrescriptions, patient access, medication overviews and more

Marco added that health is probably the best field to reap the benefits of AI. Early risk prediction is another part of AI. He said that healthcare has specificities when it comes to applying AI - including data sharing, algorithms that can be trusted and reliable, and the need for trust in the whole process.

Turning to cancer, he said the goal is to be able to cover the full spectrum, from diagnosis to survival, paediatric oncology, cardiomyopathy, plus how to access data and use it.

Marco gave examples of projects funded:

- AI for health imaging - €35 million
- Funding for improving diagnosis, treatment, follow-up and
contributing to a more precise and personalised management of cancer

- AI for genomics and personalised medicine - €35 million

- Accelerating the uptake of computer simulations for testing medicines and medical devices - €27 million

- Personalised early risk prediction, prevention and intervention based on AI and Big Data technologies - €27 million

He said there will be more to come through the Digital Europe Programme (€9.2bn) to advance digital skills, cybersecurity and trust, and to enhance digital transformation and interoperability, AI, and high performance computing.

Marco pointed out that DG Connect cooperates closely with DG Sante on Horizon Europe and data sharing, as well as regularly cooperating with other DGs.

Toine Manders, (above) MEP, said that: “Everybody needs personalised medicine. That's the only way to keep people alive, people over 50, people want to be 50-plus.”

On AI he said that “all my colleagues are really excited about AI, but in the US and China, they are miles ahead”.

Meanwhile, on the importance of Big Data, Toine said that “my colleagues are very excited about GDPR, privacy, using satellites to connect, use Google, Apple, Microsoft…”

“We are not allowed to exchange data, whereas Google always knows where we are. But here in Europe, we can’t exchange data,” he said.

If people are healthier, he said, “we can reduce the impact of healthcare and use the public money for other things such as reducing VAT for non-processed food, promoting culture and sports,” and so on. A cola bottle has a lower VAT on it than a toothbrush, he pointed out.

Toine also felt that Member states are becoming more protectionist. It should be Europe first, he said.

Bruno Wohlschlegel, head of Europe at Merck, said: “We are at the meeting point between medicine and research. It’s a vibrant area.”

Personalised medicine, he said, is about having the right medicine, the right sequence of medicine, in the right combination, the right timing, and the ideal dosage for each patient in front of us.

“This day the forbidden area is big data...we like the approach of the Commission to create a healthcare area where data can be shared, to incentivise the usage of smart health services, and to foster and promote the development of smart services,” he said, adding that: “Europe will play an important role in that field worldwide.”

Mario Romao, of the EMEA Global Public Policy Team at Intel, told attendees that “AI covers several type of activities. AI encompasses Deep Learning and machine learning. The idea is to have devices that can operate like humans.”

“For this to happen,” he said, “you need to feed the machine with millions of pieces of data, and millions of images to get somewhere meaningful.”

He added that some fear that AI will take their jobs. But he said
that, in the healthcare sector, this will not happen any time soon. "Machines will support humans but not replace them."

He went on to explain that today, we face a "data deluge" in healthcare, with healthcare accounting for 30% of world data production.

"By 2020," he said, "One ‘smart’ hospital will generate more than 3,000 GB of data per day So we need to make some policy on that. The value of AI will only thrive with good regulation."

"We need trust. There is a correlation between the availability of data and the trust," Marco added.

He explained that Europe needs a coherent strategy for AI in healthcare but, so far, no countries have such a strategy.

The digital revolution will probably happen even if we don’t do anything, he said. "But a policy transformation is required to reap the benefits."

Mario continued: "The approach should be to establish a health data space while preserving privacy. The challenge should be to digitalise healthcare - 100% digital in five years.

"We must stay strong on ethics, but ethics are already at the centre of medicine. So, I believe healthcare is prepared to adopt AI. Of course, it is important to involve all stakeholders."

Mario pointed out that, according to a study published by the OECD, the cost of non-digitalisation (not only on health) represents a lack of €800bn for OECD countries.

**Public health**

On the topic of public health, **Stephen McMahon**, Irish Patient Coalition, also highlighted Big Data and AI, saying that it is information that is going drive patient safety.

"Big Data will be a reality tomorrow, and patients have the right to access that. Equal access to treatment is a key right for patients in Europe, to give the care that patients need."

But he said that we are in the "Wild West" when it comes to digitalisation, with questions such as who own the data? This is going to be a big debate, he said, insisting that patients "are actually the architects of what is going to be built. We need to work together to build this new healthcare system."

Stephen added that it is going to be disruptive, and some changes are going to occur.

**Barbara Moss**, (pictured next page) also a patient representative, of Digestive Cancers Europe, said that: "Prevention is the best way to control and stop cancer, through a healthy lifestyle and diet," emphasising the need for efficient screening to improve early diagnostics, and raised awareness of screening programmes.

All countries should have a strategy firmly in place, as this saves lives and money.

Many patients are not getting the right treatment and diagnostics, she said. Too much money is wasted on the wrong treatment. Barbara asked whether it is ethical to give a drug that we know is not efficient to a patient?

On how to improve screening programmes, Barbara told the assembly that it is crucial to raise awareness of symptoms and screening programmes, but also very important for the GP to recognise the symptoms. More training of GPs is needed, she said.

**Indridi Benediktsson**, policy officer, DG research, at the European Commission, (pictured next page) spoke about the understanding of personalised medicine at the EU level as, explaining that it is perceived as "a medical model using characterisation of individuals’ phenotypes and genotypes for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".

The Commission, Indridi said, has been funding personalised medicine through Horizon 2020 and other multi-annual frameworks. These have included research and innovation projects in the field of cancer, genomics, research and innovation. But recently, there has been a shift in the funding, which is more-oriented towards translational research.

There is a misunderstanding on personalised medicine that we want to tackle, said Indridi, in that this is not an expensive medicine for the rich, nor is it only genomics. "We want to help people have better access to medicine, but also to increase disease prevention," Indridi said.

Attendees heard that only 25-80% of patients respond to common drugs. We also know that 5-7% of hospital admissions are due to bad drug reactions. "We need to change our mind-sets, a one-size-fits-all approach is not working any longer."

Prevention should be given more focus, the audience heard. Although the EU doesn’t have a mandate to organise healthcare, it can act on improving cooperation and sharing good practices.
At the end of the session it was concluded that there is a need for:

- **Increased efforts to make sure research results are translated into efficient medical practices**
- **An alignment of supply and demand in personalised medicine**
- **More cross-border collaboration, alongside inter-disciplinary collaboration and the involvement of stakeholders along the healthcare continuum**
- **Harmonised strategies to update the curricula of future healthcare workers**

**Translational research and bringing innovation into healthcare systems**

Kaisa Immonen, Director of Policy at the European Patients Forum, explained that personalised medicine can play a key role if it becomes equally and timely accessible for all. Half-a-million deaths could be prevented thanks to prevention and early diagnostics.

Kaia said that progress in science is happening but that innovation takes longer to reach the patient. Some people need to use crowdfunding to get money to pay for treatment, because it has not been integrated in healthcare systems. The challenge is to bring innovation directly to patients.

The procedure to assess the value of a new treatment is not working efficiently, Kaisa said. We need more coordination between Europe and Member States. The evidence requirement between those two levels are often different. We need more coherence.

It is confusing, frustrating, not fair, not transparent, too expensive, or not available across countries. Some countries are against a mandatory uptake of HTA, making it hard to have a vision for the future, both for the patients and the industry, she said.

“Only by avoiding duplication and having a mandatory uptake that will we help patient have better and equitable access to treatment.”

Talking about the impact of the patient, Kaisa said this is greater when they are involved at an early stage.

“We need more patient engagement in clinical trials. They need to be involved (and) this should be made a requirement. And we should include quality-of-life data in clinical trials.

Patients must be involved at all stages of treatment development - research, development, trials, marketing authorisation, reimbursement and pricing decisions.”

There is a need for a debate on what patients want and need. What is a fair return on investment? How are pricing and reimbursement schemes being designed? The patient must be involved at all stages and must co-design the treatment. We need more transparency and more participative research and authorisation, the attendees heard.

Mark Lawler, (pictured next page) Pro-Vice-Chancellor and Professor of Digital Health at Queen’s University, Belfast, spoke about cancer and data.

Mark told the audience that: “We need to think differently about healthcare. Healthcare is changing quickly but the healthcare systems are lagging behind and must adapt to these changes.

“We can already use data to thrive better healthcare and improve prevention, too. However, only 3% of healthcare budgets are spent on prevention (while) every three minutes one person dies of cancer in Europe.”

Expanding the theme, Mark said: “We need to bring together patient groups, researchers, clinicians, industry, and regulators to collaborate and share data. This is important to make bridges between disciplines. This should be a co-development process including citizens and patients.
“We need a social contract to use the data responsibly and effectively that embeds ethical rigour in the process.”

He spoke about a new initiative in the UK, namely DATA-CAN. This is a health data research hub for cancer, working with cancer registries from the 4 nations. The idea is to ensure fair value for all - patients, the NHS, academic researchers and industry together.

“Only a fair value will help reap the benefits of personalised medicine, while ensuring sustainability of healthcare systems and equality of access for patients,” Mark said.

He added that data is also an opportunity to better understand and tackle disparities within regions and Member States. He explained that mortality rates differ across Europe and we can use data to improve the numbers. Data gives us the ability to put forward policy recommendations that can change the situation, he said.

Mark emphasised the need for accurate data to inform the evidence to drive policy change and introduced the concept of empowering a virtuous data circle for personalised medicine, a data ecosystem founded on the ability to use and share data to drive improved care, while also encouraging research and innovation.

Prof Lawler highlighted the challenges that cancer patients face every single day of their lives and how cancer inequalities in Europe are not acceptable and need to be addressed.

While the US has developed a Cancer Moonshot to advance cancer research and care, Mark argued for a less technocratic, more patient-centred approach that is not just for Europe's elite, but rather for the entirety of the 730 million citizens that inhabit the European continent.

**Day Two**

Denis addressed attendees asking the big question: how do we facilitate an environment for personalised healthcare in Europe?

He spoke about preventive programmes and diagnostics, asking how do we identify the patient earlier, given that only 3% of Europe's health budgets are spent on prevention?

Denis also asked: How do we set a mutual framework to empower data? How do the multi-stakeholders talk to policy makers? How does can an evidence framework help? And what decisions should be made in the European Union to tackle these issues?

**Peter Liese**, MEP, offered his congratulations to the attendees, many of whom have worked for years for the improvement of European health policy.

“Today,” Peter said, “we are in a situation where the health agenda is a real priority for politicians in Europe. In contrast to the past, the health commissioner is now more concentrated on health, while he or she used to be more focused on food safety, working conditions, etcetera.”

“Ursula von der Leyen, the first woman to become president of the Commission and also the first medical doctor in the role, gave a speech in Strasbourg in which she stressed the importance of healthcare in Europe.”

On cancer, a Commission priority, Peter said: “There are concrete arguments in favour of Europe taking action. Cancer is not one disease but also sub-diseases that are quite rare. Patients need to be treated accordingly. This is an argument for more coordination between Member States.

“It is important to avoid duplication and to mutualise results. Cross-border cooperation is key - that’s why this is a European issue.”

On data, the MEP mentioned cancer registries. He said that, in Germany, “we have regional cancer registries, I visited one few weeks ago. But already at this level, there is a lack of cooperation among regions. They don’t use the same standards, methods or definitions, which makes mutualisation difficult.”
“That shows the need for a common European approach so that we can compare and share data,” he said.

On HTA Peter (pictured) said: “We urgently need to find a solution. We need to reach an agreement on this so that we can use resources more efficiently, to avoid repeating the same things in different Member States and to give access to the results to countries that are lagging behind.

“I want to convey this message to the future German presidency - please try to solve this issue before the German presidency. The HTA proposal is not the best one, unfortunately in Germany, France and other countries, as they have a Pavlovian reflex when they hear “Europe and health”. They rise against it. I really hope we’ll find a solution.”

Peter also spoke about the soon-to-happen implementation of the medical devices regulation.

“Notifying bodies have so far not been able to cope with the work they have. The European Council took a wise initiative, which was approved by the ENVI committee in the Parliament,” he said.

“The idea is to put priority on high-risk medical devices - such as implants - and to give a longer delay for low-class medical device to be studied by the notifying bodies. This will give more time to adapt, both for industry and the notifying bodies.”

“Notifying bodies must be fit for purpose,” the MEP said. “Unfortunately, some of them are not prepared enough. This needs to be tackled. Brexit will make it harder, as some notifying bodies are in the UK, so this will have to be negotiated after Brexit, too.”

Moving onto research, Peter said that Member States are cutting resources in this area. “This is bad news. This is a crucial responsibility of Member States in supporting healthcare. Member States support traditional policies, but they are not investing in the future. The future is research.”

He added that Parliament wants to increase research resources - Horizon Europe - and that health should be a priority.

“It is important to convince health ministers to stop cutting funding for research at national level. Furthermore, whatever we do, it is important to cooperate on health research on health. European cooperation is crucial,” the MEP said.

**Ortwin Schulte**, Head of Health Policy Unit at the German Permanent Representation, started with the hot topic of HTA. he said: “I think it will be possible to put HTA into a legislative solution at the EU level. A majority of Member States are quite in favour of an ambitious solution, but those covering most of the population are not in favour of mandatory dispositions.

“Given the majority rules at the Council, we need a compromise. Not only sovereignty is an argument against the current proposal for Poland, France and Germany, but also the issue of the cost containment.”

On access, Ortwin said that one of the pillars of the EU is the social rights of its citizens. The three future presidencies of the EU will be focusing on access, so I feel there will be more proposals on this in the future.

He pointed out that there will be some “challenging discussions following Brexit”. US and EU trade discussions could make things more complicated on health, too, he said, adding that the upcoming German presidency plans to hold an EU-China summit in 2020 that will include health issue.

At the international level, the EU can’t replace Member States, but both the Finnish and German presidencies believe it is important to increase dialogue with the WHO, and the process has already begun.

Under the German Presidency, Ortwin said, there will also be an important debate on tobacco and new tobacco products. “It makes sense that the EU follows the tobacco convention which will take place in 2020.”
EAPM 3rd Annual Congress:
Forward together with innovation: The importance of policy making in the era of personalised medicine

3-4 December, 2019
University Foundation
Stephen Robbins, Scientific Director, CIHR Institute of Cancer Research in Calgary, Canada, spoke about his country’s role in personalised medicine. He said: “Personalised medicine is commonly understood as providing the right treatment to the right patient at the right time. I would also add to this definition “at the right location, by the right provider and at the right cost”.

“This includes the equality dimension to the definition of personalised medicine, which makes quite some sense given the geography of Canada, but also of Europe.”

Stephen told the attendees: “The CIHR is the largest research body in Canada dedicated to improving the health of Canadians. It partners with over 250 organisations (including charities, hospitals, universities, local governments, and academics).

“In 2012 the CIHR launched the personalised medicine initiative to enhance health outcomes through patient stratification approaches by integrating evidence-based medicine and precision diagnostics into clinical trials.

“This programme progressively aligned to another programme on eHealth - the eHealth innovation service - to become the personalised medicine initiative in 2016.”

Added Stephen: “As we went forward, the team became more and more complex and multi-sectorial. Everyone has his or her own niche and brings input in the network.”

He mentioned that there are several projects on genomics, another on rare diseases, for example. Meanwhile, a focus was put on working across provinces and to put collaboration at the centre.

Regarding Canada’s experience on data and trust, Stephen said that it is quite similar to Europe. There have been some advancements with the establishment of a national data platform in recent years, which allows the sharing of data among provincial authorities. Genomic projects had to encompass legal and ethical perspectives, and that helped to build trust.

Orphan regulation

Chair Alastair Kent (next page with panel) explained that the Orphan regulation came into force 20 years ago. Since then, he said, it has been hugely successful, with many drugs gaining marketing authorisation. But just because a drug is authorised doesn't necessarily mean that a patient has access to it.

“We need to build collaboration,” he said.

Tilly Metz, MEP, told attendees that it is estimated that about 30 million people living in the European Union suffer from a rare disease.

“Since the adoption of the orphan drug directive, between 6,000-7,000 rare diseases were identified in Europe, (and) this is a good indicator of the incentive to innovate in this field.”

“However,” Tilly said, “we don’t hear enough about ultra-rare diseases that affect one-in-50,000 Europeans. They must be part of the debate despite the small numbers of patients affected.”

The MEP stressed that the debate on personalised medicine and the debate on rare diseases should not be mixed.

“Otherwise, we risk hampering the development of therapy for rare diseases.

“They should be treated as two different frameworks. Removing special incentives on rare diseases is risks endangering patients.”

“There is an urgent need to raise awareness on rare diseases, especially for children, so that patients can get access to diagnostics in specialised centres more quickly,” she said.

Simone Boselli, Public Affairs Director at EURORDIS, told the audience that, since the adoption of the Orphan regulation, around 6,000 rare diseases have been identified that affect around 25 million Europeans. 72% of rare diseases genetic, Simone explained, adding that: “The Orphan drugs regulation is a success if we look at the original objectives - 175 drugs have been approved so far.”
“However,” Simone added, “only a small percentage of rare diseases have an authorised product on the market, so a large number of rare diseases still need to be addressed.”

The audience heard that Europe has all the elements for accelerating the access to diagnostics and treatment. The European joint programme on research on rare diseases brings together everyone under the same umbrella. The council recommendation, and EU initiatives, have contributed to the creation of 25 national plans.

On ultra-rare diseases, Simone stressed that cooperation at EU level is crucial, adding that policymakers are being asked for:

- A structured cooperation in the EU, on collecting data, supported by real-world evidence
- Patients to be put at the centre of the policy

Birutė Tumiene, of Vilnius University, said that due to the unique features of their diseases, rare disease patients face major health inequality. There is a limited ability to recognise the disease, and to provide care at a primary and local medical contact point.

Diagnostics, treatment, and long-term care are also complex.

The average time to be diagnosed is five years, with some diseases un-named and un-diagnosable.

Birutė said that there is a long and difficult pathway that imposes a huge burden on the patients, as well as their family. Organising care is time consuming and hard to manage. Meanwhile, 7-in-10 patients have stopped their professional life.

Highlighting European Reference Networks, Brute explained that 24 networks and 950 centres of excellence in rare diseases kicked off in 2017.

“This is the largest platform for clinical and translational research in rare and complex diseases,” Birute said, adding: “It also allows economies of speed, scale and scope for multiple tasks, develops and implements rare disease clinical guidelines, collects cohorts and data of rare-disease patients, create a curriculum for relevant education, performs ultra-rare disease clinical trials, and monitors rare diseases for policy decisions.

Meanwhile, a clinical patient management system involving an eHealth platform in 27 languages, allows virtual consultations with specialists.

But, said Birute, there are many challenges: “We need to integrate the European network into national systems to reap its...
benefits. It is hard for patients to find their way in the European network. There are some pathways in France and Scandinavia for some rare disease which set a good example."

Tackling rare diseases implies undertaking disruptive innovation, the audience heard, not only in the treatments and therapies that are developed, but also in the organisation model.

Disruptive innovation in healthcare creates new networks and new organisations based on a new set of values, involving new players, which makes it possible to improve outcomes and other valuable goals, such as equity and efficiency.

This innovation displaces older systems and ways of doing things. However, "When innovation is disruptive, there is reluctance and resistance," said Birute.

**Daria Julkowska**, assistant director at institute GGB, EJP RD/IRDiRC, explained that IRDiRC is an International rare diseases consortium, covering rare disease strategy in research globally.

The Commission is part of it, as are many Member States, patient organisations, industry, and research bodies. It was established in 2017 with the goal of enabling people with rare diseases to be diagnosed and have access to therapy within one year of coming to medical attention.

This is a new business model, Daria said, to advance innovation in rare diseases and help patients have better access to diagnostics and treatment.

The European Joint Programme on Rare Diseases (EJP RD) gathers together universities, hospitals, patients, research institutes and infrastructure in 35 countries. It supports basic research, with €30million per year, for multinational projects.

The idea, explained Daria, is to bring research and development to patients with rare diseases. As there are still unmet medical needs and given the complexity of the rare diseases areas, there is a need for a strategic vision, and horizon scanning.

There is a common strategy of investment in rare diseases' research, as well as a data base, funded projects, and constant reviews to identify the areas where investments are needed, Daria told the audience.

"The virtual platform brings together data, standards and tools to make it usable and available globally, to mutualise knowledge on rare diseases."

Daria explained that there is global cooperation, European cooperation, and specific collaborations for example with the US-based Clinical Path Institute.

"This is a very important moment", Daria said, and "we must take advantage of what we are developing today to advance in the future."

**Maciej Gajewski**, (above) head International government affairs and policy at Alexion, told attendees that the orphan drug regulation was an important incentive in Europe for rare diseases. The environment of rare diseases has evolved in the
last 20 years, and there has been an increasing number of drugs registered.

The regulation has also allowed the establishment of a link between national systems, with many countries referring to the regulation in their national legislation to facilitate access to patients.

The success is not only evaluated by the number of products but also by the increasing activities of the pharmaceutical companies, Maciej said. At least 142 companies have at least one drug in development for rare disease, and there is an innovative environment now, thanks to the regulation.

Maciej said: “We need to think very carefully at the way we revise this legislation. We have to look at the perspective of a 10-year horizon when we start any project in research and development.

The incentive is the market exclusivity…representing an expense of 800m per year in research and development for 20 rare disease drugs.”

“Affordability and access is not inside the regulation, only the incentive. It has to be taken into account if the regulation is to be revised,” Maciej said, adding that 250 SMEs in Europe are involved in RD. But there is also the key role played by charities in this field.

**Evidence framework**

Christine Chomienne, (above) of the University of Paris, told the audience that doctors have always practiced personalised medicine, integrating both the disease’s characteristics as well as the patient’s characteristics.

A GP takes into account the age, gender, lifestyle and history of a patient when he or she treats him or her.

“But,” said Christine, “I have never asked about the wealth of my patient to make a treatment decision so far, as we always took reimbursement for granted. But this is not true, reimbursement depends on several parameters (such as) the healthcare system, private health insurance., and so on…”

Reimbursement (for treatment and/or a diagnostic) is a decision taken at Member State level, she said. After Approval by the EMA and the national authority, usually a national body gives recommendations regarding pricing and reimbursement, and then the health ministry takes the final decision, based upon
several criteria based on data, literature, publications, clinical trials, meta-analysis, etc.

“As personalised medicine develops,” said Christine, “this evaluation and reimbursement decision process becomes more and more complex. We need to prepare up front to this evaluation, while involving all stakeholders in the process to avoid refusal due to lack of evidence.

“We need to make patients and practitioners aware and involve them in the process to make good decisions on reimbursement and pricing to ensure access to personalised medicine.”

Christine explained that, in France for instance, the process involves approval by EMA, and the ANSM (the French authority), then the high authority of health (haute autorité de santé) gives its advice regarding reimbursement by the state. The French ministry of health gives the final decision.

There is an evidence framework to assess reimbursement, but this must be adapted and implemented to really help personalised medicine take up, she said.

“We must design comparative trials taking into account the new tools that we have. We should also prepare the private companies to prepare up front, publish and report in a transparent manner. If it is not all transparent, it will not be taken into account,” Christine said.

“It is not possible to keep the same evidence framework as before, the system has to adapt to new methods. And given the new complexity, it is important to do the preparation up front,” she said.

Beata Jaglielska, of the Polish Alliance for Personalised Medicine, told attendees that personalised medicine is the first targeted therapy for melanoma treatment. The outcome of patients has changed completely, and overall survival as completely different when compared to chemotherapy.

Personalised medicine would not have been possible without the discovery of DNA and the subsequent development of DNA sequencing, she said.

She described the ‘perfect therapy’ for a policymaker as one that is cost effective, whereas for a patient it’s a therapy that works.

“Personalised medicine is a milestone on the way to value-based healthcare, to reduce the burden of healthcare on society,” Beate said.

Jan Korbel, of the European Molecular Biology Laboratory, Heidelberg, told the audience that: “One of our mandates is to facilitate research and collaborative research. If you don’t share data, you multiply and isolate the data. It’s better to mutualise to process and create more value in genomic medicine. Sample sets are small, so by combining them it gets more interesting”.

“In Germany,” said Jan, “there is not enough sharing within the country. We should share more.

“We need to consider, for sharing data, a standardised format, interoperability, and the willingness to share.”

Jan added that he has been leading a study of for six years, which is close to its end, and will be published in February. “This project shows the value of sharing data,” he said.

“We are currently applying for fundings in genomic research to enable institutions to share more data in Germany,” he added. “Patients with cancer are not worried about sharing data. We
worry for them, but they don't. They would give their consent to share their data outside of their country.

“However, we have an obstacle - data sharing contracts are often prohibitive (risk of misuse of data, infrastructure needed, etc) with penalties that are prohibitive. This is discouraging and hampering research.”

Gabriele Grom, (above) associate vice-president for central eastern Europe at MSD, posed the questions: What do we call evidence? For whom? What evidence matters to patients?

“We have made progress in recent years when it comes to defeating cancer. Overall survival rates have doubled in lung cancer. There is no innovation if there is no value for the patients, and it should also be accessible to the patients;“ Gabriele said.

Gabriele added: “However, there are important disparities among Member States for access to cancer care. Only a few countries provide timely patient access to new oncology medicines.

“These differences can be explained partly by the price but there are other important factors. In Poland, new treatments are reimbursed. In Hungary, reimbursement is only based on pricing. In order to ensure more secured access, we should look at good practice - from Belgium for instance.

In Slovakia, over the last 10 years, only two new cancer medicines have obtained reimbursement authorisation.”

“But economic growth is good in these countries, so we can hope that things will improve for patients in the coming years. But, sadly, the national health budget in these countries is relatively small, with the share of GDP spent in health half the EU average. Investment in society is too low.

“Access to treatment is not only about affordability. Access is also linked to the willingness to prioritise health as a policy,” Gabriele said.

On HTA Gabriele said that it is the way forward to ensure better access to treatment and better allocation of resources at the national level.

The evidence framework must meet patient need, so that innovation reaches patients faster. Patients must have access to drugs that bring value to them. Meanwhile, patients and industry must work together. The current model is not fit for the future.

Gabriele added: “Let’s always consider the value for the patient when we consider evidence for equitable access for patients across Europe.”

Biomarkers, molecular diagnostics and the public health dimension

Hans Peter Dauben, of RFH, Germany, told the attendees that reducing uncertainties of treatment is the most important issue. Whatever makes it safer is welcome in the system.

“In Germany, we reimburse everything until it is proven that it is not safe,” he said.

He added: “We must reduce the burden of having to read everything. For instance, just reading the abstract of a publication instead of the entire text. We need to trust the paper work, so that we don't have to review. Less paper work helps not only clinicians, but also the patients - 30 page-long contracts for the confidentiality of data for instance.”

On evidence-based medicine, Hans Peter said it is a clinician
who takes the most accurate information about the disease and the patient, then combines it with his or her skills to be able to propose a treatment tailored to the patient. It is important to describe it in the right way so that the patient also understands that a treatment might not be good for him or her.

Hans Peter said: "We talk about disease, but not enough about health. We have to move to a healthy-citizen view, putting more emphasis on prevention. Genetically, we should talk about the citizen in his environment, to protect him and his health."

**Laetitia Gambotti**, Director at the Département Recherche Clinique INCa, explained that many predictive biomarkers are available for target therapy for different cancer types. Ten years ago, she said, the goal was to provide the best nationwide quality molecular diagnostic tests for all patients.

"A network involving 28 regional centres was set up, partnerships were signed with laboratories, hospital research centre etcetera," she said, "(and) in 2013, we launched another pilot programme on the implementation of targeted next-generation sequencing that involves 11 molecular genetic centres.

"The programme includes training programmes to adapt skills to new technologies, share information, and guidelines and good practices. We also have opened five screening centres for BRCA - with 1100 patients screened in two years.

"Patients should have the same access to the best treatment available. These programmes and the organisational framework enable equality of treatment, no matter what the location of patients is."

Laetitia stressed the need to raise awareness about biomarkers and diagnostics, and organise prevention and screening campaigns. "We need to inform citizens before they are patients," she said.

**Paul Naish**, (above) Director, Oncology Advocacy and Government Affairs at AstraZeneca, said that the example of the UK shows the consequences of policy on biomarkers - the funding for blood tests was paid by different organisations depending on which test was run. As a result, there was different access to the tests.

"We need to have a long discussion on the availability and access and the challenge of biomarkers in order to have it delivered. It needs to be supported by clarity," Paul said.

He listed many challenges in respect of personalised medicine, including:

- Funding challenges: infrastructure and training
- Reimbursement: the treatment is covered most of the time, but the diagnostic is often not reimbursed, whereas a timely and accurate diagnostic saves a lot of money
- The need for collaboration
- Process for approval, certification: we have to make sure this is not in the way of patient access
- Communication, understanding for practitioners but also patient information, awareness and understanding
- There is a need to develop guidelines

He suggested that EAPM and ESMO follow up by emphasising that patients need to have proper information, and their expectation needs to be met. "We have a massive to-do-list for next year," he said.

This includes asking the Commission to help mutualise data and knowledge, and for more cooperation.

Other actions are needed at national level as well as constant cross-border exchange and collaboration.
“We all agree about the challenges, but we don’t know what the priorities are,” he said. “We need more conversation and common definition of our objectives.”

**Benjamin Gannon**, VP Intl Access, Policy & Advocacy at Myriad, told attendees that prognostic biomarkers tests enable understanding of how a disease will progress and whether immunotherapy or chemotherapy is required.

Surprisingly, he said, genomics is a word on the lips of most politicians. Every health body wants to execute a biomarker policy, but getting into the details, the lack of a clear definition of biomarkers, prognostic diagnostic, makes it hard to define a policy.

He explained that the number of genetic tests available today on the US market is more than 75,000, and ten more come to market every day. However, there is the big challenge of understanding what this is about and for policymakers to regulate.

**HTA and access**

**Tiemo Wölken**, MEP, told attendees that “the European added value of the HTA proposal is obvious. It will avoid duplication, enable a better allocation of resources, and minimise the risk of fragmented access to therapy across Member States”.

Tiemo spoke about the need “to recall that reimbursement and pricing are not covered by the proposal and that will remain a competence of Member States. EU cooperation is needed to ensure constant exchange of information between HTA authorities in the EU”. He reminded attendees that Germany and France are blocking the proposal for subsidiarity concerns, “but we should act now, as the EUnetHTA is coming to an end”.

“ENnetHTA is doing a very good job,” he said, “but the voluntary basis doesn’t benefit patients. The HTA proposal will improve the situation across Member States too, (and) this is another argument in favour of the regulation.”

“We need to minimise the risk of fragmented access to therapy across Member States and sustainable healthcare systems,” the MEP added.

**Flora Giorgio**, (above) head of sector HTA, DG SANTE, at the European Commission, explained that the objective of the HTA proposal is to reduce duplicity, promote convergence, strengthen quality of HTA across Europe, ensure the uptake of joint outputs in Member States, and ensure long-term sustainability.

“The proposal,” she said, “sets up a collaboration framework of HTA. This is also about ensuring appropriate evidence for HTA across the EU. We know this is doable, we know that it is useful, but we need structure to ensure this is efficient.”

Flora reminded attendees that the proposal includes disposition to prevent conflict of interest and ensure transparency. It brings the possibility of consulting stakeholders, on specific or horizontal issues, to associate experts, as well as expert patients.
This is an important element that needs to be explained further, she said, adding that many stakeholders don’t seem to grasp the added value and knowledge that patients can bring.

“Their expertise of their disease is a crucial element, and their involvement in the process is also key to their empowerment. But involving the patients is not a given for everybody,” Flora said.

She went on to explain that disposition for a structured cooperation with regulators is included in the proposal, as well as for cooperation between the pharmaceutical industry and the EMA. There is a framework to share information in a transparent and secure environment.

“We want a common set of evidences,” she said. “These are national agencies working together, not a European assessment top-down. This is not the final decision. The joint HTA will not replace the national body for reimbursement. But we need a joint methodology. That’s what the EUnetHTA is already doing. This is not easy, but it is working.”

**Marcus Guardian**, Chief Operating Officer at EUnetHTA, said he was “so excited” when parliament passed amendment to the original proposal, and that it is very hard to understand the complexity of the political system.

“We need a framework for collaboration beyond the HTA proposal,” said Marcus.

“Without a collaboration framework, there is no way we are going to deliver. With voluntary collaboration, we made some advances, but at this stage, we need a more robust framework.”

“Based on the collaborative work on HTA, access for patient has dramatically increased,” Marcus added.

**Tanja Valentin**, Director External Affairs at MedTech Europe, explained that, all-in-all, there are about 500 different types of medical devices on the market in the EU - covering companion diagnostics, in vitro diagnostics, apps…from prevention, diagnostic, to treatment.

She said: “We support the objectives of the HTA proposals, and recognise the added value of the EU action. On the use of HTA in medical technology, this is not a tool that is very much used, less than 1% of innovation coming from medical technologies are concerned by HTA.

“Most medical devices are designed in France, Germany, Switzerland and the UK,” Tanja added.

What methodology, what data should be used, is a big question mark in the collaboration. This needs to be addressed. If not, HTA at EU level will be just a huge cost for something that remains on the shelves, but is never used, she explained.

“Having the same question, the same need, is what brings people together. Finding this common denominator is the key to collaborating. When it comes to HTA, we need to make Member States understand that they have a common need,” Tanja said.

**Agenda items for the new political term (2019-2024)**

**Petra De Sutter**, (above) MEP and chair of the IMCO committee, told the audience that the internal market is important for health, and the EU freedoms that we want to serve. They are at the centre of the European project.
However, the market is still fragmented, she said, especially the health market. Industry has trouble accessing the market, and patients have trouble accessing treatments across border.

Petra said: “Regarding personalised medicine, the IMCO committee is very much interested in the regulation of data sharing, the collection and transfer of data while protecting the rights of the provider of the data, meaning the patient/consumer/citizen. This will be a very important issue that concerns the health sector as the new Commission has put the digital single market as a priority for the coming mandate. We need to tackle the fragmentation of the market.”

“Trust is a key issue for data sharing,” Petra said, and “that concerns the future of personalised medicine in Europe. I’m confident that Parliament will support the work of the European Commission on this. We really need to act now, in five years, it will be too late. If Europe doesn’t act now, other players will fill the room”.

On data and genomic data, Petra spoke about the need for a framework to use them in a correct way. “We want to protect citizens’ rights, patients’ rights… Is GDPR enough? What about non-personal data? And anonymised data?”

“When it comes to DNA, it is not very possible to anonymise data. How to share it with industry? The more data we have the larger opportunity we have, but we need a purpose for the data. Furthermore, sharing data for healthcare is not used enough because of the reluctance of Member States to give up this competence in favour of the EU.”

Regarding the stratification of patients, Petra said that a final-stage cancer patient might not have the same will to share his or her data than someone in a prevention phase.

“Sometimes, we need to protect patients against themselves, some could be tempted to accept trials and experimentation even against human rights. We must put safeguards for the use of data. The general interest must be represented in this debate,” she said.

Petra explained that she had recently had a debate with telecom operators regarding trust.

“The operators want the legislators to help build trust,” she said. “If we manage to build trust, we will make a difference. If not, in 10 years, other players would have taken over the room. We really have to do this now, it will be too late in 5-10 years.”

Benjamin Horbach, (above) Health Systems Strategy Leader –
Personalised Healthcare at Roche, said: “We are in the partnering phase right now, stakeholders are collaborating more and more, and this is a good thing.

“I can see opportunities and challenges for the future of personalised medicine in Europe. The current discussions on interoperability of data, real-world evidence to close the evidence gap, plus the need for an infrastructure for the mutualisation of data, are positive signs that will turn into opportunities.”

“The challenges concern the pathways to integrate personalised medicine into healthcare, the development of a framework for biomarkers and how to support the necessary transformation of the healthcare systems,” he said.

“We need to raise awareness on personalised medicine…(and) build a consensus among stakeholders, from patients, academics to industry and governments.”

Benjamin added that: “The key is the empowerment of patients, and to fulfil the right of patients to have access to diagnostics and to an appropriate treatment at the right time.”

Jasmina Koeva, (above) Chair of the Board, Bulgarian Alliance for Personalised and Precision Medicine, said that, from the perspective of a small country, one of the poorest in the EU, with a very small annual health budget of €2.5 billion to diagnose and treat a population of seven million, it makes it quite hard for personalised medicine to be taken up.

However, she said: “In the last two years, there have been improvements. If we cannot rely on the support of the healthcare ministry, which is not designed to support innovation nor to encourage the implementation of innovation therapies, we have instead found support in the minister for education and science.

“Medical universities are more willing and have run projects,” Jasmine said, and have built centres of excellence on personalised medicine, co-financed by the Commission.

“Those are the places we rely on for the development of precision medicine in Bulgaria,” she said.

She explained that a few years ago saw the inception of a Balkan network on personalised medicine (Romania, Bulgaria and Macedonia), plus the second Balkan conference on personalised medicine, which had the involvement of new countries Croatia, Cyprus, Slovenia and Greece.

“We had guests from the Finnish presidency, and the support of Mariya Gabriele, the former Bulgarian Commissioner, who gave the opening speech. There is new attention being given to personalised medicine in this part of Europe. This is a positive and inspiring moment,” said Jasmina.

She outlined key challenges going forward, citing that Bulgaria needs the EU to provide guidelines and more financial support for infrastructure, for screening and diagnostics, in particular for a cancer screening programme. “We intend to continue our effort in that direction,” she said.

“The EU could be of great help for countries like ours,” she said. “Furthermore, prevention medicine is currently not far developed nor financed in this part of Europe.”

She finished by talking about trust. “The way to build trust,” she said, “is through constant communication and bringing stakeholders together.”
Forward as one into 2020: EU Presidency tri-conference programme

The European Alliance for Personalised Medicine is delighted to announce the first of three EU Presidency-themed conferences for 2020.

These will be, firstly, during the Croatia Presidency, followed by a bridging conference between the Croatia and Germany presidencies, and a final event while Germany is at the helm.

The Croatia conference will take place in Brussels from 23-24 March.

Not only do these conferences reflect the nature of the relative presidency policies in the healthcare arena, but also act as major events during what will be the first full year of the two new legislative bodies - the European Parliament and the European Commission.

Croatia has already outlined four key priorities for its turn as EU President - a role it takes over on 1 January, 2020.

While healthcare is not mentioned specifically at this stage, several issues will have an impact in that arena.

Croatian Prime Minister Andrej Plenkovic highlighted "a Europe that connects", and said that Croatia’s four prioritised goals are a Europe that is growing and developing, a Europe that connects economically, energy-wise and infrastructure-wise, a Europe that protects and a Europe that is globally influential.

The prime minister stressed that a “Europe that connects” is needed and that it is therefore necessary to further develop transport, energy, and digital infrastructure.

“We will stand for a Europe that protects its citizens while respecting and protecting the rule of law,” he said.

The presidency slogan will be: “A strong Europe in a challenging world“.

Bridging conference - Croatia and Germany Presidencies
Maintaining public trust in use of Big Data for health science

Brussels
30 June 2020

Personalised healthcare brings us the opportunity to put citizens at the heart of decision making, including communicating openly about what happens to data, who is using it, and what level of control people can, or cannot, expect.

We can apply ethical rigour every time data is used, shared or transferred to safeguard individual privacy, and ensure data is secure and provide guarantees that data will not be compromised by breaches that reveal personal information.

We can ensure that the public has trust in data science, especially for large scale initiatives that enable significant breakthroughs in our understanding of human disease.

We can underpin public trust by advocating the value of health-data research to society and promote the need for robust, trustworthy and ethical approaches to deliver new health advances for our citizens.

Generally speaking, one of the great challenges to reduce both late-stage incidence and mortality is early diagnosis. But it has to be reliable. In this conference that bridges two Presidencies of the EU (Croatia and Germany), the emphasis is on public trust in health data and its uses.

One of the great opportunities to reduce both late stage incidence and mortality is early diagnosis. But it has to be reliable.
"Everybody needs personalised medicine. That’s the only way to keep people alive, people over 50, people want to be 50-plus"

Toine Manders,
Member of the European Parliament

“We are at the meeting point between medicine and research. It’s a vibrant area”

Bruno Wohlschlegel,
Head of Europe, Merck

“There is no innovation if there is no value for the patients, and it should also be accessible to the patients”

Gabriele Grom,
MSD

“Member States support traditional policies, but they are not investing in the future. The future is research”

Peter Liese,
Member of the European Parliament

“The way to build trust is through constant communication and bringing stakeholders together”

Jasmina Koeva,
BAPPM

“There is an urgent need to raise awareness on rare diseases...so that patients can get access to diagnostics in specialised centres more quickly”

Tilly Metz,
Member of the European Parliament
Looking ahead to the next two decades, there will be a massive increase in cases of cancer in Europe.

Regulators, industry and healthcare professionals really need to step up to this new reality, and this also applies to citizens, who have a certain degree of responsibility for their own healthcare.

Lifestyle changes will be paramount, and could amount in many cases to the best form of prevention.

Stopping smoking, cutting down on alcohol, getting off the sofa and exercising, eating the right food - it all helps. Adhering to medicine regimes isn't a bad plan either…

However, biomarkers have a job to do, too, in modern personalised medicine. We need more of these that are relevant to treatment.

Certainly, we're churning out lots of data, but as more clinical trials and large scale epidemiological studies take place, new technologies such as blockchain will be urgently needed to handle the data.

And this has to be done without infringing regulations surrounding data protection (namely the General Data Protection Regulation (GDPR)).

Unfortunately, the barriers in respect of data sharing mean that risks related to data security and privacy can have a paralysing effect on progress.

One of the goals of EAPM events is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process, while also aiming to showcase developments and new ideas.
About EAPM

The European Alliance for Personalised Medicine was launched in March 2012, with the aim of improving patient care by speeding development, delivery and uptake of personalised medicine and earlier diagnostics, through consensus.

EAPM began as a response to the need for a wider understanding of priorities in personalised medicine and a more integrated approach among stakeholders. It continues to fulfil that role, often via regular major events and media interaction.

Our stakeholders focus not just on the delivery of the right treatment for the right patient at the right time, but also on the right preventative measures to ensure reliable and sustainable healthcare.

The mix of EAPM members and its broader outreach, 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, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.

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

EAPM's Congress made possible through the generous support of: