



European Alliance for Personalised Medicine

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EAPM Sofia success as own Congress nears

Welcome to our November newsletter, as we move into a particularly busy part of the year, not least with the new European Commission moving into the Berlaymont on the first of the month.

Coming up very soon is, of course, **EAPM's 3rd Annual Congress** (3-4 December) and you'll find more details about this major event within this newsletter.

On top of that, as you will by now know, Brexit Britain has (sort of) been given an extension, and we'll find out this week until when. Will we see an end to it all before 2020? Who knows?

What we can reflect upon now is that the British Government, via **Michael Gove**, says it can guarantee that people's health will not be adversely affected by the UK's departure from the EU in the event of a no deal.

Gove said this in the House of Commons despite Prime Minister **Boris Johnson's** own government's updated '*Operation Yellowhammer*' no-deal planning paper stating that without mitigation delays at ports could "have an impact on the supply of medicines and medical supplies".

Gove told the House that while there were "undoubted challenges that we face in leaving the EU", "ensuring medicines supply was "one of the areas where the greatest amount of mitigation has taken place."

Concerns remain regarding goods crossing the Channel. But Gove insisted that "appropriate steps have been taken to ensure we have maximum level of flow..." adding that "if all businesses are ready, that means that flow for everyone is easier".

He added that the Department of Health and Social Care and the Department for Transport have also put in place additional freight capacity for vital goods including medicines.

However, the UK's National Audit Office (NAO) has warned that essential health and social care supplies could be disrupted by a no-deal Brexit at the current state of preparations.

The NAO chief, **Gareth Davies**, said he was "obliged to point out the work that still needs to be done and the risks that remain".

He cited the "incomplete information about the level of stockpiles in place" on the part of the Department of Health and Social Care, even though the latter has been amassing key medicines and securing warehouse space. Some 7,000 of the 12,300 medicines used in Britain come from or through the EU.

In the EAPM pipeline:

- **8 November: Pioneer General Assembly, London**
- **14 November: EMUC Congress, Vienna**
- **3-4 December: EAPM 3rd annual Congress, University Foundation, Brussels**

Official sources estimate that, in the worst-case no-deal scenario, the flow of goods across the Channel could instantly be reduced to 40-60% of current levels.

The majority of Britain's pharmacists had already said they believe that a no-deal Brexit will worsen medicines shortages, in a survey by the Pharmacists Defence Association. From a total of 1,071 pharmacists surveyed, 81% felt that medicine shortages would get worse in the event of a no deal, with 55% saying they would get "much worse".

Irish unity on healthcare

Ireland has published a bill to protect its neighbouring Northern Ireland residents' access to EU emergency care benefits in the event of a no-deal Brexit.

The bill will operate in a similar way to European Health Insurance Cards, but with Ireland providing the reimbursement. **Simon Harris**, Ireland's health minister, has called for the legislation to pass by the end of the month so that from 1 November, "arrangements are in place if needed".

Staying with Ireland, former Irish MEP and EAPM champion **Marian Harkin** is set to chair the group All Policies for a Healthy Europe, which will renew its call for the Commission to make health a priority. It has released a paper called the '*Economy of Well-being & EU Economic Governance*'.

Sofia so good

Unlike, arguably, Britain's bid to leave the EU, our co-event in Sofia on 24-25 October was built on realistic, clearly defined and solid foundations, in this instance ably assisted by the Bulgarian Alliance for Precision and Personalized Medicine (BAPPM), in collaboration with the Medical University Pleven, and the Bulgarian Society of Human Genetics and Genomics.



SMART

Smaller Member States And Regions Together

This key conference - *Forward Together in the Personalised Medicine Era* - took into account the broad impact of personalised medicine and, given that no Member State can realistically go it alone when it comes to modern-day healthcare, noted that the vital question is how to move forward.

The conference dovetailed perfectly with EAPM's now long-running '*SMART Outreach*' strategy (with SMART standing for Smaller Member states And Regions Together) and brought together representatives from a broad stakeholder base drawn from across the Balkans Region and beyond.

Bulgaria's own **Mariya Gabriel**, who over the past five years has done an excellent job as European Commissioner for Digital Economy and Society, and is soon to be Commissioner for Innovation and Youth in the upcoming **Ursula von der Leyen** administration, was with us in Sofia and warmly greeted.

She was very upbeat about international collaborations as well as highlighting that €35 million of investment will be opened this month for this domain.

One of the incoming Commission's key missions, she reminded attendees, is fighting cancer, and Ms Gabriel spoke about the need to firmly set goals in this regard and to develop close international collaborations, while pushing the frameworks of digital health hubs across the bloc.

Member State collaboration is clearly key, as she emphasised by saying that the integration of personalised medicine into EU healthcare systems requires "interdisciplinary cross-border collaboration and effort from everyone".

Bulgaria's Deputy Minister of Education and Science **Karina Angelieva** told the audience that her country has been a successful partner in the bio-banking sector and is an established Balkan leader, although a stronger network with the Western Balkans is necessary.

She cautioned, however, that: "Investments are in vain if a broad collaboration is not established and operational. Collaboration and cooperation is essential."

BAPPM chair **Dr. Jasmina Koeva** said: "Cross-border collaboration is vital and, with this in mind, countries here in the Balkan region are aiming to work side-by-side to develop a coherent action for public-private collaboration between the relevant countries, creating a model that others may follow."

She added: "There are solid arguments that what we need is more, not less, Europe - and for practical purposes that means less silo thinking and more cooperation, across borders and across disciplines."

Finland currently holds the rotating EU Presidency of the EU, and Finnish geneticist **Tuula Helander** took to the conference floor to explain that there are a cluster of centres of excellence under development in Finland, and gave the example that her country aims to be a source and user of high quality and versatile scientific research, inventions and innovations.

She also emphasised the importance of "leveraging health data required to accelerate personalised medicine and the health sector".

During *Day Two* in Sofia, attendees heard a talk by **Ciaran Nicholl**, of the Joint Research Centre Ispra, at the Commission. Ciaran highlighted the fact that Europe has the potential to develop the best guidelines through collaboration and contributions from each Member State - a theme running through the conference.

He also explained that the European Breast Cancer Guidelines are being finalised, and will be launched and rolled out (alongside a quality assurance scheme) next year. It will give a 2020 vision to tackling breast cancer at the EU level with the support of Member States, Ciaran said.

Beata Jagielska, of the Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology in Warsaw, told attendees that value-based healthcare - in which providers such as physicians and hospitals, are paid based on patient health outcomes - has advantages for patients, providers, suppliers and society as a whole.



It encourages hospitals to improve health services, she said. Beata went on to posit that cancer should perhaps be classified not according to the tissue it affects (breast cancer, colorectal cancer, and so on) but as molecular cancer.

Either way, she said, we need more cooperation between EU countries for the implementation of cancer networks, as well as a discussion on new definitions of cancer, so as to take into account its molecular nature.

She added that the Polish Alliance for Personalised Medicine is very supportive of the MEGA+ initiative on sharing health data and looks forward to further cooperation when it comes to developing evidence frameworks.

Rositzta Krasteva, Chief of the Oncology Center "UniHospital" in Bulgaria, talked about the great progress in cancer treatment in the 20th century, adding that precision medicine is the future of oncology, while Jasmina Koeva gave a summary of the Human Genome Project, calling it "the largest international research project in the world".

The attendees also heard that 30-40 million Europeans are affected by rare diseases, and that no single European country can currently produce 1 million genomes by itself.

Borut Peterlin, Head of the Clinical Institute of Medical Genetics, Ljubljana, Slovenia, spoke about genomics in healthcare, and the public health challenge of rare diseases.

Among many points, Borut emphasised that clinical symptoms and signs of a certain clinical/differential diagnosis need to correspond to the genetic finding.

The genomics expert added that the majority of Slovenian people would like to know if their partner is a carrier of a genetic mutation, and also emphasised that no EU health system is the same and, therefore, best practices need to be standardised across the bloc.

And **Draga Toncheva**, president of the Bulgarian Scientific Society for Human Genomics and Genetics, spoke about prostate cancer, pointing out that it is one of the most common cancers with a 57% heritability rate.

Draga added that Bulgarian Guidelines for Action in Patients with Prostate Cancer were set up in 2019.

Meanwhile, **George J Netto**, Chair of Department of Clinical Pathology, University of Alabama at Birmingham in the US, offered up lung cancer as a paradigm for precision pathology.

He said that recent technological and interdisciplinary advances present unprecedented opportunities for precision medicine, while changes in the healthcare sector pose challenges, but at the same time open new doors.

And **Sven Seiwerth**, Head of the Department of Pathology, University of Zagreb, Croatia, spoke about predictive biomarker testing in his home country.

He explained that prognostic biomarkers provide information about the overall cancer outcome, regardless of therapy, while in the case of predictive biomarkers, healthcare professionals can glean information about the effect of a non-surgical therapeutic intervention.

As the conference wrapped, EAPM's executive director **Denis Horgan** (above) hailed the event as "a great success, and proof positive that collaboration works in all aspects of personalised medicine, and is certainly where we need to go".

Around the EU...

While we were busy in Sofia, the world didn't stand still - far from it. News is just in that clocks will continue to change (as they did this weekend), until at least 2021.

And over in Germany (which, but the way, wants an end to daylight saving time), it's good news for a software called 'Vara', which has been developed by a Berlin-based AI startup and uses artificial intelligence technology to find breast cancer in mammograms.

It has just obtained the CE mark, the health and safety standard benchmark for products sold in Europe.

The developers will soon trial Vara in pilot projects in cooperation with doctors and health insurers, while negotiating



with the latter about including the software in the services they reimburse.

On the broader topic of artificial intelligence, EAPM will publish its own paper on AI in the personalised medicine era during the next month. The crucial issue of prevention is also covered.

Meanwhile, the Finnish Presidency of the EU has brought out its draft Council Conclusions, which highlight issues that EAPM has long championed, including a cancer plan.

This is long overdue after the European Partnership for Action Against Cancer of almost a decade ago, and the question of how to translate plans into tangible action remains. The key now, as the Finns have noted, is to ensure sustainability and availability of health services for medicines, as well as a surge forward in molecular diagnostics.

The plan which, as we know, is fundamental to the new Commission's agenda, looks to support EU countries in their efforts to "prevent cancer, address early diagnosis and treatment, and improve the lives of patients and survivors".

The draft also calls on the EU to support countries "through appropriate actions within its competence, in their endeavours to improve the sustainability and availability of health services, including access to medicines and medical devices".

Finland's draft conclusions go on to note the "shortages and high prices of a number of medical devices and medicines" that, combined with inefficiencies in using generics and biosimilars, "can threaten the sustainability and financing of national health systems".

The conclusions also highlight the need to improve access to - and the cost-effectiveness of - medicines, and call for continued discussions on affordability and security of supply.

On top of this, Member States acting through the Council of Ministers have told the Commission to continue funding European Reference Networks (ERNs), while developing the e-health Digital Service Infrastructure.

This enables the voluntary cross-border exchanges of patients' health data.

ERNs, the virtual networks gathering knowledge on rare diseases across the EU, need simplified financial and administrative procedures plus a reduced administrative burden, as well as continued finance with a view to their long-term sustainability, say the Member States.

EU health chief sets her stall out

The European commissioner-designate for health and food safety, **Stella Kyriakides** (above), says that new business models and the "right incentives" to develop new antibiotics are needed in the fight against antimicrobial resistance (known as AMR).

In her written responses to the European Parliament's ENVI committee, Kyriakides promised to work in particular with the commissioners for the internal market and research "to encourage the development of new business models fostering innovation on new antibiotics".

The commissioner-designate has also recently commented on the increasingly troubled issue of health technology assessment.

With some health attachés currently talking about the increasing pressure being put on the Commission to rethink the EU-wide mandatory aspects of HTA, as far as Kyriakides is concerned, the (now 20-month-old) proposal on health technology assessment is something for which she will seek consensus, but doesn't intend to climb down on. It's "obvious that the voluntary way is not working", she said.

In July, Finland's EU presidency submitted a discussion paper tackling some of the most controversial elements of the original proposal, including the scope of therapies subject to EU-level HTA; ways to ensure the quality of the joint reports; the use of joint assessments; and whether that report is ultimately included on a list of assessed joint technologies.

Meanwhile, **Belgium** has also got its teeth into the use of joint assessments, suggesting that Member States "shall consider" or



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“shall take into account” such aspects. **France** and **Germany** are keen on the provisos, but only if it’s clear in the text of the regulation that individual governments get to decide which aspects of the joint report are relevant to their national process.

The two EU heavyweights only want 10 joint clinical assessments per year to start with.

Also, Paris and Berlin have suggested leaving conclusions out of any joint clinical reports, calling for scientific report descriptions only, with no value judgment.

The latest is that health attachés have been discussing options relating to the most controversial aspects. A paper from the Finnish Presidency has noted that: “Most delegations do not agree to the obligation to use JCA reports and the non-duplication thereof, as proposed originally by the Commission.”

It seems to be the case that Member States agree that their national HTA bodies shouldn’t ask developers to re-submit the same data used for the EU-level HTA, and that they should “incorporate” the joint report into the “evidence base” for their national HTA.

The Finns have tabled various options to bring the EU countries closer together, which means keeping the obligation to avoid duplication, but sharing any data submitted by pharma companies voluntarily to a national HTA body on an IT platform, deleting the Commission’s role in making a joint report official in another section of the proposal (Article 7), which would effectively eliminate the requirement to use the joint work.

Instead, the only rule would be not to duplicate the requests, and further requiring Member States “to avoid unnecessary duplication of work done at EU level.”

As justification, the Finns note: “If this obligation is added to the previous one/ones it would contribute to increase the value-for-money of work done at EU level.”

More from Kyriakides

Noting a call from the pharmaceutical industry and EU countries for fresh incentives to come up with new antibiotics, Kyriakides said: “We need to create the right incentives for the development of new antibiotics while safeguarding their prudent use.”

The incoming Commissioner also mentioned the need to encourage development of new vaccines, which could be part of the solution against AMR.

On cancer treatment she said that patient outcomes in response to treatment and the way they experience care need to be measured “in a more systematic and rigorous way”.

Regarding medicines shortages, Kyriakides pledged to work with EU countries and the industry to mitigate these in Europe when it comes to “inexpensive essential medicines” and “highly innovative, expensive medicines”.

In the meantime, she believes that increasing the evidence base across the EU “will help to inform national decisions on new medicines”.

EMA and transparency policy

Notes from an European Medicines Agency board meeting recently said that a move from European Court of Justice Advocate General **Gerard Hogan** may mean that the “EMA’s existing transparency policies would be impaired and have to be revised”.

In 2018, the General Court of the EU ruled that the EMA was right when it granted a rival pharmaceutical company’s request for access to a clinical study report from PTC Therapeutics. But the latter is appealing against the decision and Hogan disagreed with the court’s ruling that the reports aren’t confidential, adding that disclosing the report compromised PTC Therapeutics’ commercial interests.

Hogan has recommended that the Court of Justice send the case back to the General Court for review.



Regarding EMA's transparency policies, they've been "moving in the right direction," according to the senior health policy officer at consumer group BEUC, and the opinion from Hogan "threatens the public's right to know" about the safety and efficacy of the medicines they take.

BEUC's policy officer said that: "Any move that would force the EMA to take a step back from its current practice would be extremely regrettable."

EMA extra

News from the European Court of Auditors (ECA) is that the relocation of the EMA from London to Amsterdam is expected to cost €17.8 million.

Every euro-cent will come from the EMA budget, according to **Rimantas Šadžius**, who is the ECA member heading-up the audit into the EMA and all other EU agencies.

At the start of Brexit negotiations, the Commission planned to ask the UK to pay all the costs related to the agency's relocation. It later binned the idea.

The fear is now of a possible decrease in the EMA's revenue post-Brexit and the ECA said the lack of certainty about the total loss of staff following the agency's relocation represented "a significant business continuity risk".

If this were not bad news enough for the EMA, the auditors gave it a telling-off for not yet making fully effective measures to decrease "the excessive use of consultancy services" for two IT projects.

These relate to implementing EU laws on pharmacovigilance and clinical trials.

"The Agency should speed up the implementation of mitigating action not only for the completion of the ongoing IT projects, but also to get ready for significant new projects such as the implementation of the Regulation on veterinary medicinal products and the Regulation on medical devices," the ECA said:

Šadžius did temper the criticism of the agency, though, acknowledging that the EMA has worked to decrease reliance on external consultants.

Medical devices grace period

It has been well-reported that the EU will allow a subset of legacy medical devices to stay on the market until 2024, which could keep crucial devices in use whether or not they've been approved under the new regulation that enters into force in May next year.

MEP **Peter Liese** (pictured), a long-term friend of EAPM, has already said that it was a "good compromise" and that Parliament will support it.

Progress on implementing the incoming regulation has been undeniably slow, with only five notified bodies officially online ahead of the May 26 deadline. It is clear that some issues still remain to be solved, frustrating both industry and regulators alike. Meanwhile, the Finnish Presidency says it is working on a paper about medical devices.

Clinical trials regs back in the news

There is also a lack of progress on the Clinical Trial Regulation of five years ago. Missing is an independent audit of the functioning of the information system. This is according to **Kristof Bonnarens**, of DG SANTE.

The audit needs to be given to the EMA Management Board, which will then tell the Commission that the system is working. When will the audit take place? Well, the Commission will conduct an exercise to determine the date.

SANTE on investment

Staying with DG SANTE, its chief **Anne Bucher** says that it's not only more investment in health that Europe needs, but new forms of it, which involves moving away from the traditional hospital-centred approach towards investment in new medicines and hospital equipment for community-based care, new patient pathways and integrated care services.

Bucher added: "We have to support the adaptation and training of the health workforce and the digital equipment and ICT services for data sharing and HTA," as such investments are more relevant today for facing future challenges.

Meanwhile, the Structural Reform Support Service, which was created in 2015 to help Member States with expertise in major



reforms, is set to become a Commission directorate-general. So said **Géraldine Mahieu**, who is head of unit in charge of the health and social services, the labour market, and education. She pointed out that the service has this far supported 57 healthcare projects in 21 EU countries.

Mahieu added that **Spain, Portugal** and **Greece** are currently being offered technical support to improve affordable innovative medicines.

Smoke signals

Speaking of Greece, the government in Athens is looking to ramp-up its smoking ban. The health ministry is drafting a law to broaden the ban's scope and hire more police officers to enforce it. The plan is to extend the ban to open-air public venues and clubs, with a €200 fine for those naughty enough to defy it.

And in Germany, outdoor tobacco advertising restrictions, plus new rules on e-cigarettes, are currently under consideration.

Progress planned on digital

Also in Germany, Berlin says it will go big on digitalisation during its Council Presidency from July 2020. The trouble is, its own system is out-of-date. Due to politics within the country, it's behind many smaller countries who are already exchanging e-prescriptions, for example.

Health Minister **Jens Spahn** (above) faces resistance over requiring German health insurers to pay for apps helping patients manage chronic diseases, and the security of patients' data in respect of the costly job of encoding patient records.

Austria rejects joining scanning initiative

Austria has declined to join the International Horizon Scanning Initiative (IHSI), which was created as a spin-off of BENELUXAI, and is the only one of the group to do so.

The reason? "Due to internal reasons the Austrian Ministry of Labour, Social Affairs, Health and Consumer Protection decided to not actively take part in the IHSI, but we are looking forward to learn more about the outcomes," it was reported by *Politico*.

The job of IHSI, which includes the likes of Sweden, the Netherlands, Belgium, Ireland, Luxembourg and Canada, will be to monitor upcoming innovative treatments and look at how to pay for the new therapies.

3rd Annual Congress open for registration

EAPM is pleased to announce that registration for its 3rd Annual Congress is now open, and you can book your place at the 3-4 December event in Brussels [here](#)

This year's Congress will be held at the University Foundation in the Capital of Europe and, while we may not be able to solve all the problems that Brexit will surely bring, we certainly will be aiming to further the goals of personalised medicine for the benefit of Europe's patients, hopefully with your input!

Brussels has been chosen to host the event as the new Parliament is of course now in place, while the next European Commission will very shortly have its feet firmly under the tables of the Berlaymont under its new president.

The theme of the event, under the auspices of the Finnish Presidency, will be "*Forward together with innovation: The importance of policy making in the era of personalised medicine.*"

Congress will showcase different objectives which both the public and private sector can support, with a view to allowing the EU to present a common objective.

As always, the Congress will be in a focused format to allow concrete issues to be tackled and to have a dialogue with our policymakers, and is a follow-on from the past two successful editions in Belfast and Milan, as well as our seven well-attended and influential annual conferences.



Around 1000 Life Sciences thought leaders are expected to convene and, as in the past two years, the event will bring together key audiences who contribute to the vast programme content and vital knowledge exchange.

One of the goals of Congress is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process.

Europe needs to grasp the fact that health equals wealth and that investment in research and innovation, alongside laws and rules that are fit-for-purpose and reflect the swiftly changing world of medicine, are vital. Hence our continued interaction with MEPs, Commissioners and Member State health leaders.

So what's on the table this year?

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

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

A drinks reception and dinner will close the day with speakers looking at public health genomics in the personalised medicine era, and the key drivers in the healthcare arena.

Day Two should be full and productive with sessions on the current hot topic of the orphan regulation, evidence frameworks, plus value-based outcomes and biomarkers.

As you may recall, biomarkers were discussed recently at an EAPM satellite event held at the Barcelona **ESMO Congress**.

Of course, there remain a number of key challenges that need to be met to ensure genomics and related technologies

are applied such that we can fully realise the potential of personalised medicine to improve health care and reduce costs.

Biomarkers are important here, being characteristics that are objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

Meanwhile, also discussed in Barcelona were ways to create a framework and networks to develop an environment to facilitate personalised healthcare quicker and faster.

Access for all citizens is key and, among other components reliable, concrete real-world evidence can facilitate this.

Further investment in the development of methodologies and a European repository for evaluation methods and evidence of digital health services should be encouraged.

EAPM and its stakeholders have emphasised the importance (as has the Commission) of data interoperability, particularly in the context of collecting, sharing, and manipulation of data and recommended the use and development of international classifications and terminologies to increase interoperability.

On top of this, Member State governments could play a more active role in the further optimisation both of the process of decision-making (both at the central and decentralised level) and the related outcomes.

A further hot topic at Congress - HTA and reimbursement - is sure to bring about a lively debate, while the final session of the two-day event on 4 December will seek to provide agenda items for the new political term running from now until 2024.

It all promises to be a lively, informative and productive couple of days, so don't miss the opportunity to join large numbers of industry professionals, government regulators, patients, academia, and exhibitors to drive insights to action.



Alliance to run triple presidency events

With a look to the future, as always, EAPM is planning considerable engagement with the two **EU Presidencies** coming up in **2020** - namely Croatia and Germany.

And, as usual, this will be partly achieved through key, high-level events, taking in the Member State presidencies as well as input from the European Parliament and a broad range of stakeholders, including industry.

Croatia takes over the EU Presidency in January 2020, so EAPM is hosting a steering group event on **24-25 March**, with the main topics geared around gene sequencing, early diagnosis and the broader aspects of health innovation.

EAPM will also host a bridging conference between the two presidencies on **30 June-1 July** - titled "*Maintaining public trust in use of Big Data for health science*" - as well as a German Presidency conference on **29-30 September** under the banner "*Building a decentralised, data-rich biomarker space to speed better cancer care*".

All three events will be held in Brussels. More details to follow.

In the news

As ever, the Alliance has been busy engaging with the media. Below you can find links to recent articles.

[Gabriel impresses, and Boris stonewalls](#)

[Balkan States look to work together on personalised medicine](#)

[Balkans big on enlargement and healthcare agendas](#)



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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.

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