



European Alliance for Personalised Medicine

EAPM Bulletin: Issue 54, September 2019

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Von der Leyen moves to build new Commission

Greetings, and welcome to the September newsletter from EAPM. Back to work we all go, and hopefully you've all had a good break. Busy times lie ahead...

Certainly very busy at the moment is incoming European Commission President **Ursula von der Leyen**, who is assembling the College that will form her top team for the next five years

And, of course, Brexit took yet another turn this week with the decision by UK premier **Boris Johnson** to prorogue Parliament during a significant chunk of the run-up to Britain's departure from the EU on 31 October.

But more of all that later as we'd first like to draw your attention to an important document that the Alliance has put together recently.

It takes the form of an **MEPs briefing** and aims to inform both new and returning Members of the European Parliament about the background to personalised medicine, where things currently stand in the sector, and what's expected and/or required as we go forward.

At 50+ pages it's pretty comprehensive while still being written as much as possible in layman's terms. The briefing is available for all to download [HERE](#).

The document will be distributed around Brussels, in particular the European Parliament, and made available to our colleagues and experts attending the ESMO Congress (see below).

Barcelona, such a beautiful horizon...

Coming up pretty quickly, on 27 September in fact, is the prestigious **ESMO Congress** in Barcelona at which, for the fourth time, the Alliance be hosting a satellite roundtable meeting as part of the events.

In the same way as our own many conferences and congresses, the focus will be on bringing innovation into healthcare systems, but with very specific items on the Alliance agenda.

EAPM's event at ESMO will, for obvious reasons, have a cancer focus, with one aim being to see how we can facilitate bringing personalised healthcare into the EU's healthcare systems. The Alliance believes that a field as large as oncology can illustrate best practices for use in other disease areas.

A further key focus of the event will be to align and explain the broader personalised healthcare story to the wider community.

In the EAPM pipeline:

- **27 September: EAPM roundtable at ESMO Congress, Barcelona**
- **28 September: Pioneer roundtable (as above)**
- **16 October: MEP Roundtable, Brussels**
- **4-5 December: EAPM 3rd annual Congress, Brussels**

We already know that the drivers of personalised medicine are clear for each stakeholder group: patients; the pharmaceutical industry; and for healthcare systems and payers. But many ask whether innovation is really giving us value for money.

The debate has focussed to a large extent on the cost of "doing something" – the spiralling cost of developing drugs, the extra cost of providing innovative diagnostics, the hidden costs of supportive care.

But among other things the EAPM meeting will ask is "what about the cost of not doing something?"

If we ration healthcare we must do so in a logical way. This will mean making tough decisions but these decisions must be made on rational evaluation of an evidence base that evaluates both cost and value. We need to prioritise approaches that will deliver cost-effective quality care that will improve the lives of European citizens and societies.

While we need to reward innovation in this context, it must be innovation that gives value to patients.

One basis for this roundtable is that it is necessary to formulate a personalised healthcare strategy involving medical specialists, decision makers and regulators in the arena of oncology public health, to enable EU and Member States to contribute to integrating personalised healthcare into clinical practice while enabling much-greater access for patients.

Attendees will be drawn from key stakeholders from the oncology community whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. Joining them will be decision makers, representatives from the

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Commission, Members of the European Parliament, patient groups, and European umbrella organisations representing interest groups and associations actively engaged in the field of personalised medicine.

The sessions will cover:

- *Oncology and real-world evidence*
- *Stakeholder perspectives*
- *Putting personalised medicine into practice*
- *Molecular diagnostics*
- *Biomarkers*
- *Patient empowerment*
- *Future-proofing healthcare*

For those of you who will be there, we look forward to seeing you in Barcelona.

Commission coming together

As mentioned up top, European Commission President-elect Ursula von der Leyen began official interviews with candidates for her upcoming College this week.

The new Commission chief is reportedly thinking about revamping the structure of the EU's Executive to give more 'oomph!' to the posts of vice-presidents.

Currently they have the title, but not much extra influence or real power, but Ushi vdL may change all that by giving vice-presidents direct access to Commission staff. That doesn't sound like much, but it would effectively give them more power to inform and set legislation.

In the previous administration, a system existed in which

portfolios were handed to five vice-presidents who were supposed to oversee several commissioners each. But they did this without direct access to relevant Commission staff, so it was largely ineffective.

Up for vice-president posts, as we already know, are Dutch Socialist **Frans Timmermans** and Danish Liberal **Margrethe Vestager**, and they can both expect more influence under the new plans.

Timmermans may well lead efforts to come up with a Green New Deal, which will cover relevant policy areas set to include transport, energy and research and development.

According to *Politico*, the reform ideas are part of an attempt to reflect geographical and political diversity in the executive's leadership, alongside bringing about much-needed better coordination.

Most of you will remember that von der Leyen came from virtually nowhere in the race to beat Timmermans and Vestager to the top job, but there needs to be a demonstrable balance of power between the EPP, the socialists and the liberals.

This may not be particularly easy and, as one senior Commission official reportedly said: "You cannot have three presidents, but you need a bizarre love triangle."

As far as the composition of the rest of the next Commission goes, von der Leyen will have a complete list of her Chosen Few in the coming weeks, after ongoing sessions with candidates.

She's already met **Margaritis Schinas**, the Greek candidate who is currently the chief spokesperson for the Commission, and has also interviewed **Helena Dalli**, Malta's candidate.

Others scheduled for meetings this week include the Czech Republic's **Věra Jourová**, Estonia's **Kadri Simson**, and **Stella Kyriakides** from Cyprus.

Visitors to vdL's office won't have included the original Polish

Old and new faces for von der Leyen Commission. Current list of nominees - Page 7

Left, Denmark's Margarethe Vestager (currently serving); Frans Timmermans of The Netherlands, centre left (also currently serving); Belgium's nominee, Didier Reynders, centre right; and; bottom, Dubravka Šuica of Croatia





candidate who withdrew himself from consideration, because Warsaw was offered the agriculture portfolio and he was less than keen, although not because the brief isn't a tasty one.

Krzysztof Szczerski said: "I think this portfolio is so important for Poland that it should go to someone who has been dealing with agriculture their whole life."

Poland's replacement nominee is **Janusz Wojciechowski**, who is currently an auditor in the European Court of Auditors. An auditor? Given the portfolio, hopefully he's more than just a bean counter, then.

The trouble is, Bulgaria has said it wants current Digital Commissioner **Mariya Gabriel** (above) for the powerful agriculture dossier, so there may be some gripes in Sofia.

Meantime, as Italy's governmental crisis rumbles on, Rome had yet to nominate its European commissioner as we finalised this newsletter. But Belgium has not been tardy, with the formerly monikered 'Mr Euro' himself, current Foreign Minister **Didier Reynders**, being named as the country's candidate.

There will certainly be no Briton undergoing an interview with von der Leyen, it seems, with the UK confirming that it would not be nominating anyone to succeed **Julian King**.

"The government has been clear that we are leaving the EU on 31 October whatever the circumstances. Given that the new Commission will not be taking up office until after we have left we will not need a new commissioner," a statement read.

Here at the Alliance we were delighted to learn, via an announcement by Croatia's Prime Minister **Andrej Plenković**, that current MEP **Dubravka Šuica** will be nominated as the country's European Commissioner.

Dubravka was a strong ally of all of us going into the Declaration of Cooperation on the one-million genomes project, so we'll keep a close watch on developments and offer support where possible.

Rumour has it that Croatia is keen on the regional policy portfolio, so there may well be opportunities for our SMART Outlook programme. Either way, we congratulate Dubravka and look forward to meeting her at some point in her new role.

As for the remaining Members of the European Parliament, EAPM is already gearing up for effective action alongside the new intake and many faithful friends who are back in the hemicycle.

Brexit latest

Sometime between 9-12 September, until 14 October, the UK's House of Commons will be prorogued (in other words, suspended) after Prime Minister Boris Johnson sent envoys up to Balmoral in Scotland - **The Queen's** holiday estate - to advise Her Majesty to do so. Protocol dictates that the monarch has to acquiesce, as she duly did.

Very few saw the move coming, but more predictable was the reaction from mostly pro-remain MPs (alongside quick-reacting public demonstrators), who accused the premier of moving to stop any attempt by Parliament to avert a no-deal Brexit. He's certainly carved up the time available.

To nobody's surprise, Mr Johnson denied it, of course. (As **Mandy Rice-Davies** once said of another high-profile political denial: "He would, wouldn't he?")

For his part, the Speaker of the House of Commons **John Bercow** called Johnson's decision "a constitutional outrage" adding that it is "vital that our elected Parliament has its say" on Brexit.

Parliament returns on 3 September, presumably so MPs can book their office cleaners and get their suits and dresses spruced up just before the re-opening and The Queen's Speech. Then off it goes to rejoice or fume for a month.

On Wednesday this week, Mr Johnson said a Queen's Speech would take place after the suspension, on 14 October, to outline his "very exciting agenda".



Boris said he didn't want to wait until after Brexit "before getting on with our plans to take this country forward".

Well, he's been a busy boy already this month. After recent one-on-ones with German Chancellor **Angela Merkel**, above, French President **Emmanuel Macron** and European Council President **Donald Tusk**, the UK Prime Minister was on the phone to soon-to-depart European Commission President **Jean-Claude Juncker** on Tuesday (27 August).

As Europe awaits solid proposals, perhaps in vain, from Britain on avoiding a hard border on the island of Ireland, the Commission reiterated, prior to the chat, that: "It is up to the UK government to come with concrete proposals that are compatible with the withdrawal agreement."

While the Commission is correct, for those of you that remember such a thing, the oft-repeated remarks are beginning to sound like a stuck record. We *know*, already!

As you will also doubtless know, The UK is due to leave the EU on the 31 October, and that date looms ever larger.

Britain has said: "Under no circumstances will we create a hard border in Northern Ireland or impose physical checks or infrastructure of any kind at the Northern Irish border. We are fully committed to upholding and protecting the Good Friday Agreement."

"The fact is the Withdrawal Agreement has been rejected three times and will not pass in its current form, so if the EU wants a deal, it needs to change its stance."

As noted, the EU remains unmoved, with Commission chief spokeswoman, **Mina Andreeva**, telling journalists that no one in Brussels envisages any positional change.

Andreeva added that: "In a no-deal scenario, the UK will become a third country very concretely without any transition arrangements."

"And that very obviously causes a significant disruption not only for citizens and businesses but also would have a serious

economic impact, which would... have a proportionately higher impact in the United Kingdom than in the EU27 Member States."

If no deal does go through, Irish officials will presumably be obliged to impose border inspections and customs duties on UK goods, as a direct result of WTO rules as well as the safeguarding of the integrity of the EU's single market.

As an interesting aside to this, a border-free solution has been put forward by the former head of a special Commission task force on Brexit, **Jonathan Faull**, alongside legal eagles **Joseph Weiler** and **Daniel Sarmiento**.

The trio suggest that Brussels and London could have independent regulatory systems and customs regimes, and make it a criminal offence for Ireland and Britain to knowingly export goods across the Irish border in breach of the rules governing the other side.

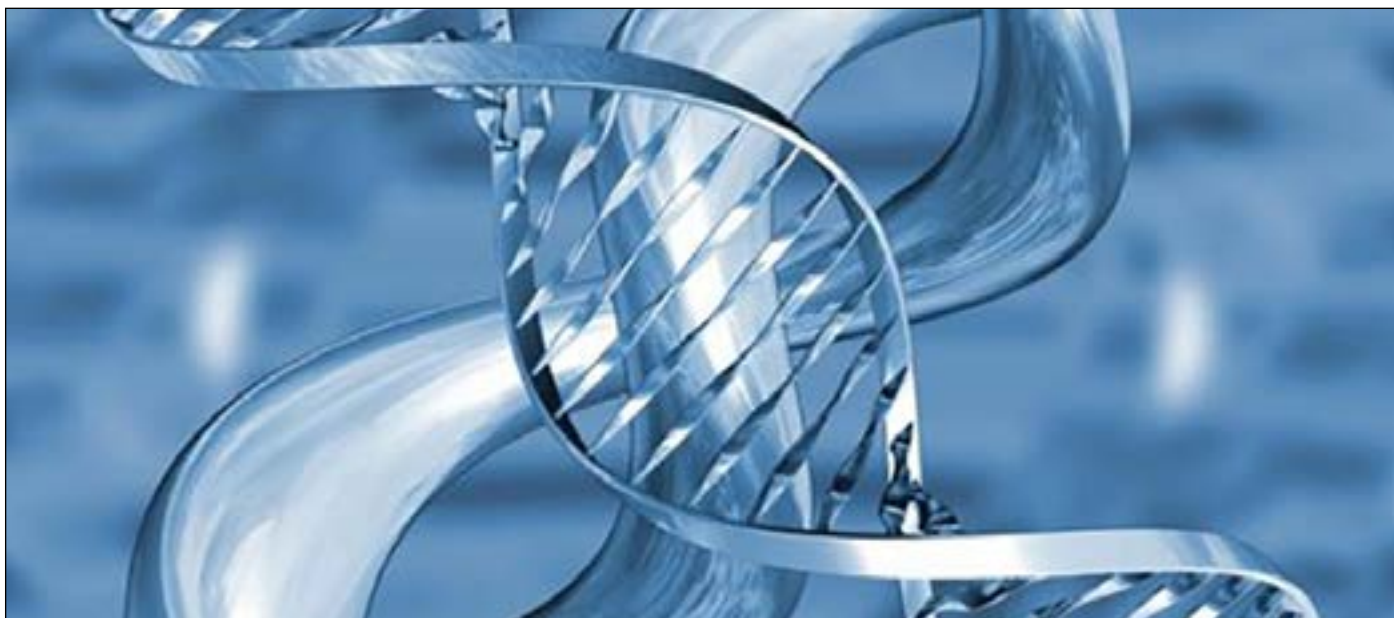
The plan would avoid customs checks by the setting up of a network of 'EU Trade Centres' across both countries.

Meanwhile, at the G7 summit in Biarritz last weekend, Johnson said that if Britain leaves the EU without a deal, it's a "simple statement of reality" that it would keep much of the +/- £39 billion financial settlement agreed by his predecessor **Theresa May** in its pocket.

Despite the fact that Johnson didn't actually say this directly to Tusk when they met, an EU response was duly forthcoming and not-at-all surprising: "All commitments that were taken by the 28 Member States should be honoured, and this is also and especially true in a no-deal scenario where the UK would be expected to continue to honour all commitments made during EU membership."

This was Mina Andreeva speaking again, and she added: "Rather than going now into a judicial action threat, I think it is important to make clear that settling accounts is essential to starting off a new relationship on the right foot based on mutual trust."

Basically, "if you want to be our mate, treat us like one."



US President **Donald Trump** was also in France for the G7 gig, and took the time to warn Boom-Boom Boris that: “The EU is very tough to do a deal with. Just ask Theresa May.”

In medical-related matters, citizens on either side of any border in Ireland could face delays and complications in accessing medical treatment after in a no-deal scenario. This is because the ability to move healthcare data across the border could stop overnight, it has been speculated.

But Prime Minister Johnson doesn't appear to be in the least bit worried about...well, anything, really, saying that Britain could “easily cope” with a no-deal Brexit. Perhaps this was partly to do with Donald Trump telling Boris that the US wants a trade deal with the UK by the summer of 2020.

Good luck with that timetable, fellas!

From Paris with love

Finally in our Brexit section this month, Johnson said during his visit to see Macron that: “Whatever happens with Brexit, it is our joint ambition, UK and France, that we should deepen and intensify our economic inter-penetration.

“And just as French buses, I am proud to say, ply the streets of London thanks to the unique openness of the UK economy, it is also a stunning fact that your beautiful TGVs run on steel railways made by British steel. Not a lot of people know that. In fact, the British ambassador didn't know that, I just told him.

“There could be no more powerful metaphor, I think, for the cultural, the economic, the political partnership between our countries.” Well, if you say so...

Although they were both very chummily waiting at the bus stop for three to come along at once, Macron wasn't leaving the shelter of EU policy when he said (yes, again): “I'll be very clear, in the next month we won't find a new Withdrawal Agreement that will be very different from what we have.”

Meanwhile Angela Merkel clarified her “in the next 30 days” remarks to Johnson at their own meeting last week: “The 30 days were meant as an example...because Britain had said they want to leave the European Union on October 31.

“Until then, we must, or we can, if political will exists on both sides, find a regime which maintains the Good Friday Agreement on the one hand...and at the same time secures the integrity of the single market.”

Was that actually a clarification, dear chancellor? OK, possibly.

Keeping genomics personal

Moving on to genomic data (see the Alliance's MEGA+ initiative, which aims to take the one-million genome further by adding all forms of healthcare data), a recent survey has taken a look at citizens' views on their DNA and potentially sharing the resulting data.

Belgian charity **The King Baudouin** Foundation conducted a survey of 29,000 EU citizens, and it's not particularly good news for pharmaceutical companies, given that only four in 10 respondents said they agree with the statement: “I'm willing to share my genetic information with pharmaceutical companies.”

Even worse, roughly one in four said they “strongly disagree”.

On the other hand, the sharing of genetic information with academic researchers is more popular, with 58% saying they would do that. Also, a hefty 73% said they want to know “as much as possible” about their DNA.

A focus group of 32 citizens, tied to the Foundation's work, meanwhile indicated that people want to be able to make autonomous decisions via informed consent. However, they will need better information about genomic data, its implications and how it will be used.

Which highlights a need, of course, for new training for healthcare professionals and more options available from health systems when it comes to preventive care.

Who's in the frame von der Leyen Commission?

- **Austria - Johannes Hahn**
- **Belgium - Didier Reynders**
- **Bulgaria - Mariya Gabriel**
- **Croatia - Dubravka Šuica**
- **Cyprus - Stella Kyriakides**
- **Czech Republic - Věra Jourová**
- **Denmark - Margrethe Vestager**
- **Estonia - Kadri Simson**
- **Finland - Jutta Urpilainen**
- **France - Sylvie Goulard**
- **Greece - Margaritis Schinas**
- **Hungary - László Trócsányi**
- **Ireland - Phil Hogan**
- **Latvia - Valdis Dombrovskis**

- **Lithuania - Virginijus Sinkevičius**
- **Luxembourg - Nicolas Schmit**
- **Malta - Helena Dalli**
- **Netherlands - Frans Timmermans**
- **Poland - Janusz Wojciechowski**
- **Portugal - Elisa Ferreira**
- **Slovakia - Maroš Šefčovič**
- **Slovenia - Janez Lenarčič**
- **Spain - Josep Borrell**
- **Sweden - Yvona Johansson**

Italy is yet to name its candidate, while there's a decision to be made by Romania between Rovana Plumb and Dan Nica. The UK is not submitting a candidate.

Defining 'fair'

EAPM has often talked about the need for definitions in healthcare - not least regarding what constitutes 'value'. Now we have a definition of 'fair pricing' in respect of medicines from the WHO.

The organisation's Fair Pricing Initiative says: "A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of quality essential health products."

Conditional reimbursement to continue?

Finland holds the current presidency of the EU, and its own health ministry wants, to all intents and purposes, to extend its experiment with conditional reimbursements in respect of some new medicines.

This is due to expire on 1 January 2020 but the talk now in Helsinki is of extending the programme until 2025.

Since 2017, Finland has approved 25 out of 33 drugs for conditional reimbursement, allowing them to work in real-world conditions before deciding whether the health system will pay. Parliament will decide on the new proposal in the autumn.

Medtech moves in Germany

The German medtech lobby hopes to heap extra pressure on EU and national policymakers to deal with implementation issues around new medical device rules.

An article in a top German newspaper has put the spotlight on the plight of small manufacturers who are having problems complying with EU regulations brought in in 2017, and these small companies have a powerful voice - making up the

majority of Germany's €30 billion medtech industry. Academics have blamed the rules for a drop in German medtech patent registrations since 2016.

EU-US health interaction

Despite US President Donald Trump's sometimes fractious relationship with many other parts of the world, it turns out that the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) have pretty good relations that include a high degree of alignment in marketing application decisions, more than 90%, in fact.

This was uncovered by a joint EMA/FDA analysis that compared decisions on 107 new medicine applications at the agencies from 2014-2016.

The study found that the most common reason for diverging decisions were differences in their conclusions about efficacy, followed by differences in clinical data submitted in support of an application.

Zaide Frias, the head of EMA's human medicines evaluation division, said: "The high rate of convergence in the authorisation of new medicines at EMA and the FDA is the result of expanded investment in dialogue and cooperation since 2003 and has fostered alignment between the EU and the US with respect to decisions on marketing authorisations, while both agencies evaluate applications independently of each other."

She added: "Our cooperation clearly supports both agencies in achieving a common goal of maximising patient access to safe, effective and high quality medicines in both regions."

In the past ten years, the agencies have established joint working groups for sharing information and collaborating, using experts drawn from both the EU and US.



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

My body is a temple

Another Eurobarometer poll is just out and sees EU citizens citing “health and social security” as one of the three “most important issues” being faced in their particular country. The other two are unemployment and the rising cost of living.

Health and social security concerns top the charts in six nations, namely Finland (48%); Slovenia (47%); Hungary (45%); Portugal (34%); Latvia (32%); and, wait for it... the UK at 29%.

Ten countries rank health and social security in second place, with the highest proportions in Sweden (42%), Ireland (41%) and Denmark (40%).

Are you listening, politicians? Well let's hope so as a further poll from Eurobarometer shows that, after this year's European Parliament elections, EU citizens have a rising trust in the bloc and increasing optimism about the EU's future.

A record-busting number (56%) said they believed their “voice counts” in the EU. If ever there were a call to duty for MEPs, then that's surely it.

As it turns out, the Brits have less faith in the EU than respondents from any other Member State, with just 29% saying they tend to trust it. Meanwhile, generally, trust in the EU beats trust in national governments by about 10 percentage points.

The EU has bigged-up the poll results, saying: “Overall, the EU is seen in a more positive light than at any time over the past 10 years.”

HTA news

The EUnetHTA Executive Board has been busy and recently adopted the following “Understanding of EUnetHTA HTA”.

Don't you just love these terms? “Understanding.” OK...

This text was worked out over several months with the project's board, and it explains that the EUnetHTA Executive Board agreed that HTA in the context of EUnetHTA activities is understood to be composed of the following elements:

- *Assessments should inform decision-making*
- *Assessments are not decision-making processes themselves*
- *Information should be of relevance to a decision-maker or user of the assessment. Wording which is overly exclusionary has the potential to predetermine decision-making, and formulations such as “no conclusions can be drawn” should be avoided*
- *Assessments should include the best available evidence at a specific given time point*
- *Assessments should specifically formulate a ‘summary of findings’*
- *Summaries should endeavour to use clear and concise scientific language*

So now you know.

Meanwhile, the Commission has followed up on the European Parliament's legislative resolution on the proposal for a regulation on HTA and amending Directive 2011/24/EU.

In essence it says that it welcomes the overall positive approach set out in the resolution, adding that while waiting for the Council position, it reserves its position on the amendments of the European Parliament.

On that note, the Commission did express concerns over



certain amendments. For those of you who are really keen, the issues arise in amendments 45, 49, 115, 116, 117, and 118. The Commission is also a bit worried about Amendment 153.

And so the HTA proposals rumble on... More as we get it.

EAPM December Congress

EAPM will be following all relevant topics at its 3rd Annual Congress on 4-5 December, which is to be held in Brussels (rather nicely depicted above) this year.

The Belgian capital has been chosen to host the event as the new Parliament is of course now in place, while the next European Commission will also, by then, be in 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 seven well-attended and influential annual conferences.

Congress registration opens in September, so very soon, and we hope to see you there!



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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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