



European Alliance for  
Personalised Medicine

## **INTERVIEWS:** MEMBERS OF THE EUROPEAN PARLIAMENT (MEPS) & STAKEHOLDERS

By Denis Horgan,  
EAPM Executive Director on behalf of the Members of the  
European Alliance for Personalised Medicine

This framework activity document for 2019 represents a mission-oriented approach to integrating personalised medicine and personalised healthcare in Europe taking into the account the EU elections and the Commission priorities from 2019 - 2024.

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## PERSONALISED MEDICINE WORKS, WHATEVER YOUR POLITICAL PERSUASION

**Welcome to this publication, which is geared towards our fellow Members of the European Parliament as well as those standing for election to Brussels and Strasbourg for the first time. All of us who have placed our signatures below have been involved with, and have supported, the European Alliance for Personalised Medicine down the years.**

As you will discover, this publication is essentially a collection of interviews, the majority with MEPs, offering insights into thought processes and covering the many and varied aspects of this radical, modern form of treatment, which makes the best use possible of the giant leaps in genetics, as well as other sciences, and puts the

patient firmly at the centre of his or own healthcare regimes. Although we are from a cross-section of different parties, a political rainbow, we are all aware that cooperation and collaboration is vital if we are to bring innovation into healthcare systems. More collaboration also needs to occur among other stakeholders. It is easy to talk about but harder to actually do, yet silo thinking in all relevant areas needs to be a thing of the past if we are to move forward in the best way that we can.

It is vital that we do this as the good health of the EU's citizens is paramount, both societally and fiscally (health means wealth, after all), and the challenges on the way to achieving this are many. These include, but are no means limited to, the need to promote innovation, the need to optimise resources

by thinking 'smart', the need to care for an ageing population suffering from more and more comorbidity and chronic diseases, the need to share research and the need to better harness Big Data.

As representatives of the European Parliament we form one legislative part of a bigger entity, the EU as a whole. Surveys have already told us that there has been a continuous increase across the bloc in citizens' support for the European Union. On top of this, around 70% want the EU to get more involved in healthcare, despite it being a Member State competence. These numbers are hard to ignore, and healthcare is up alongside other issues that citizens have identified as priorities, including security issues in the broadest sense, such as immigration, and issues related to personal prosperity. Meanwhile, the much-talked-about Spitzenkandidaten process is generally seen as more transparent and, therefore, more democratic and overall a positive development.

Most parties have already named their 'lead candidate', and the Treaty of Lisbon makes it clear that the result of the European elections should be taken into account by the European Council, when it proposes a candidate for the post of European Commission President.

The nominee then comes to us in the European Parliament for approval, with our institution voting by majority. In February of last year, in fact, MEPs called for the Spitzenkandidaten process to be applied in this year's elections. As citizens have noted, this is a democratic way forward. Unfortunately, despite the good news mentioned above about citizens' faith in the EU, on the down we have witnessed the UK reject Europe - albeit by a relatively small margin - and the 'leave' vote and its implementation will surely not help our Union move forward in many areas, including healthcare. To cite just one example, cross-border sharing of excellent research will likely suffer, for both parties.

Against this background, we must all guard against creating circumstances in which a similar decision to that taken by Britain can occur.

On healthcare specifically, the European Union as a whole has been playing a greater part in recent years, with several major pieces of legislation that have had to go through Parliament to be amended, voted upon, and pushed towards Council.

We take seriously our roles as an open ear for stakeholders and as open-minded and open-eyed scrutineers (although that is not all that we do), and each and everyone of us works hard for the benefit of the EU's citizens, despite our occasional political differences. This is why we are all happy to sign the foreword for this, the latest EAPM publication, and will recommend it to our Parliamentary colleagues, members of the European Commission and, of course, our electorate in our own Member States.

We sincerely hope you that find this publication entertaining and informative, as we all learn more-and-more each day about personalised medicine and its continuing impact on healthcare systems, alongside its undoubted benefits for current and future patients across the EU.

We may be a 'rainbow' of representation, but there is a pot of gold at the end for all patients.



**Denis Horgan**  
EAPM Executive Director

# RELEVANCE OF POLICY IN SHAPING PERSONALISED MEDICINE



In modern-day healthcare, personalised medicine is the wave of the future. But it has already emerged in the here-and-now, and its influence is growing everyday. It relies on new technologies (genomics, enhanced imaging etc), Big Data and better-targeted clinical trials, among other aspects, in order to deliver the right treatment to the right patient at the right time.

However, there are many practical barriers to be overcome, and stakeholders believe that policymakers have a vital role to play if the potential of personalised medicine is to be fully realised sooner rather than later. These areas include the need for more promotion for research, education programmes, incentives for innovators, much-better collaboration and, not least, improved regulation and commonly accepted (and widely implemented) standards and best practices.

## Why 2019 is particularly important?

This is election year. So, under the upcoming Finnish rotating presidency of the EU, we will have a new intake of MEPs in the European Parliament, alongside some well-known faces. We will also see a new European Commission put in place, with both institutions holding a five-year mandate. Prior to this, we will see the European Union lose a major Member State when the UK leaves the current EU-28.

Post-Brexit, the number of MEPs will go down from the current 751 to 705, with 46 of the 73 UK seats available for possible EU enlargement down the line. The remaining 27 UK seats will be shared out among 14 other Member States, which are currently viewed as under-represented.

From a healthcare point of view, the British decision to leave could prove to be something of a disaster for the health of almost 65 million citizens, despite empty 'battle-bus' promises of lots of cash being pumped into the NHS. And it possibly goes further than that because the 'supply lines' of research and cross-border cooperation will surely suffer on a pan-European scale after Brexit starts to kick in.

But Brexit aside, with those European Parliamentary elections coming up in May, health and healthcare issues will be high up the list of citizens' priorities, wherever they may be in Europe. In fact, around 70% of citizens think that EU should do more in this key area, despite health being a Member State competence.

It is undeniable that citizens believe that politicians of whatever hue in all Member States need to unite over a variety of health-related matters - including introducing innovation into systems and pushing preventative measures - for the benefit of all current and future patients.

Let us move forward with healthcare in the EU. With or without Britain. For this to happen, the policies formulated and applied under the new five-year mandates will be crucial.

### More EU involvement

As mentioned above, the EU's populace wants to see more involvement from the Union, and it is already the case that the EU as a whole has become more active in various aspects via legislation on IVDs, clinical trials, cross-border healthcare, data protection and, now, health technology assessment. But the EU clearly cannot act alone. Member States have to adapt, accept changes to HTA/approval procedures and collaborate much more with their fellow EU countries across borders in many spheres, including the sharing of knowledge and research (to avoid duplication), and the pooling of Big Data.

It is evident that the EU, in tandem with Member States, needs to ensure the proper transposition of its legislation and policies regulation at national level. More work needs to be done on agreeing treatment guidelines, and encouraging their implementation, quickly and effectively.

All Member States come at healthcare from a different angle, sometimes due to wealth (or lack thereof), a high (or, indeed low) incidence of a particular disease or diseases in its population, the cost of pharmaceuticals, cross-border payments to patients, the strength or otherwise of patient advocacy and more. There are often even many differences within the regions of the larger nations.

Clearly, optimal treatment is not being offered in every country and the above are only some of the reasons. Ineffective or non-existent cross-border collaboration, meanwhile, only adds to the barriers to access for patients.

### EAPM high-level engagement

Since its formation, EAPM has engaged with Parliament, the Commission, Member State healthcare representatives and stakeholder bodies on a regular basis, even encouraging the formation of the STEPs group of MEPs (STEPs stands for Specialised Treatment for Europe's Patients).

This has been done via congresses and conferences (EAPM's and others), roundtable meetings, interviews, suggestions for amendments to legislation and every other practical route.

The Alliance has received a great deal of support from many MEPs and there is no doubt that such collaboration will continue during the new legislature, with a clear focus on policy.

This methodology has proved successful in the past, not least given Alliance involvement in the groundbreaking Luxembourg Council Conclusions on access to personalised medicine, changes to legislation via amendments, and clear, consensus-built messages from EAPM's multi-stakeholder group on everything from the need for screening and standards to a compromise between protecting patient privacy while allowing for the exchange of vital medical data.

The latter is particularly important given the key role played by the Alliance in kick-starting the MEGA initiative (Million European Genomes Alliance); which aims to garner a cohort of one-million genomes across Europe for research purposes and also covers the sharing of any valuable medical data under strict privacy and ethical rules.

### Where to with policy?

So what are the core needs that EU and Member States policymakers need to address to fulfil the vast potential of personalised medicine?

Innovation is key to progress and, currently, there is a lack of incentives - increasingly post-economic crisis, a time during which

payers pulled up the drawbridge thus adding to a scenario in which healthcare systems across Europe have struggled.

As things stand, there is a deficit of incentives to promote investment in developing diagnostics. Experts say that coordinated timing when it comes to reimbursement and approval of a companion diagnostic is essential. On top of this, the transferring of technology and public health assessments differ from state-to-state, although moves are afoot to improve this.

The translation of research is another key issue. This affects both treatment once a disease has been discovered and, importantly, prevention - with all the cost savings that go along with the latter, not to mention continuation of the best quality of life.

Translating cutting-edge research effectively in the arena of personalised medicine will save lives and lower costs.

## Education

Education is another vital cornerstone. Policymakers need to fully understand the needs of modern-day patients and how personalised medicine has the potential to change healthcare for the better.

They must be aware that it is vital to develop training for healthcare professionals (HCPs) whose disciplines are essential to the successful development of personalised medicine.

Stakeholders have pushed hard for on-going training as, clearly, there is a knowledge gap that has to be addressed as we move forward scientifically and technologically.

What is urgently required, then, is a long-term approach to education in order that all HCPs in close contact with patients or their patients' families are up-to-date with the current aspects of personalised medicine and its latest breakthroughs.

## Integrating personalised medicine

From a policymaking and regulatory perspective, Europe has reached a point in the healthcare of its current 500 million citizens when clear, harmonised rules and guidelines need to be put in place across the entire European Union. These should be determined and be applied in all relevant sectors.

But none of the above can be successfully achieved without the involvement of all relevant stakeholders. These include patient groups, academics, researchers, IT professionals, industry representatives, health care professionals, HTA bodies, the EMA and, of course, politicians, policymakers and payers.

Policymakers at both EU and national level (European Commission, Parliament, Council and Member State healthcare payers) have a significant role to play in bringing about a Europe in which personalised medicine, in all its forms, can be integrated into national health care systems, via the sharing of data, cross-border collaboration in research projects, exchanging of best practices, and a seismic shift from a silo mentality, not only in the main cross-disciplinary fields but within single disciplines.

The EU cannot, as it stands, assume responsibility for all healthcare systems across Europe (as discussed above), but it can certainly recommend (as did the Luxembourg Council Conclusions) in the areas over which it does not have legal competence.

But first its policymakers must listen and thoroughly understand all of the issues affecting access to personalised medicine for its citizens.

This would go a long way to opening the door for a new form of treatment that will bring better and longer lives to many patients across Europe's borders.

## Personalised medicine and its impact on policy

Having noted the relevance of policy in shaping personalised medicine at EU and Member State level, now and into the future, what about the other way around? How has the rapid emergence of this exciting new form of treatment helped to shape policy?

The answer is 'in many significant ways'.

Advocates of personalised medicine, of which there are many - including multi-stakeholder groups such as EAPM - have engaged with various rotating Presidencies of the EU in recent years to put forward the views and 'asks' of their various expert members, which of course include patients.

Legislative engagement on the topic of personalised medicine with the European Parliament, European Commission and European Council has been key to several major pieces of legislation in recent years, as well as input into Horizon 2020 in support of the IMI and IMI II public/private partnership to aid research. All eyes now turn to Horizon Europe...

Meanwhile, the European Commission regularly drafts opinions and expert panel findings in areas that are key to the advancement of personalised medicine, such as those on access to health services, the data-driven economy and its Action Plan on Big Data.

These documents invite comments and contributions from stakeholders in the relevant arenas. Advocates of personalised medicine have worked hard to get their views across in all of these cases.

Added to this, stakeholders have contributed to the PerMed strategy, which was formulated by a Coordination and Support Action (CSA), and financed by the European Commission. PerMed is a coalition of partners representing key decision makers in research and research policy, industry, healthcare and patient organisations.

And as well as through regular interaction with the Commission, there are many MEPs (STEPs group and more) who have a strong

interest and belief in the advancement of personalised medicine, concluding that it is the way of the future as Europe stares into the abyss of an ageing population, with the inevitable increase in co-morbidity needs that this will bring.

MEPs on the ENVI, ITRE, LIBE and ECON committees all have an interest in various ways in pushing personalised medicine forward, so it's fair to say that significant sections of the Parliament have been, are, and will continue to be engaged.

Meanwhile, contributions from stakeholders to academic publications, side meetings at large health conferences, and personalised medicine conferences themselves - especially those that engage MEPs and policymakers alongside other stakeholder groups (patients, academics, IT professionals, researchers, ethics experts etc) - all help to push the agenda.

Patients these days are also doing a great deal, with many of the groups looking towards personalised medicine - and its patient-centred approach - to help make their voices heard, give them a better quality of life, engage them in decision making, and perhaps even save their own lives and, through use of their data, this lives of others.

For patients, this is a new era of knowledge and self-empowerment.

## Spreading the word

Thanks in part to EAPM, several 'outreach' events have already occurred on the ground in countries across Europe, including Austria, Bulgaria, Poland and Italy. Personalised medicine groups are starting to form across Europe and more will follow.

In the mainstream media, articles on personalised medicine, and areas that contribute to it, are being seen more-and-more often, which helps immensely to raise awareness among other journalists and in the general public.

## Making healthcare sustainable in Europe

Generally, it is clear to the EU and to its Member States that the current situation in the healthcare systems across Europe is unsustainable. Solutions need to be found, and quickly.

There needs to be a paradigm shift from the one-size-fits all model to a smarter, more sustainable way of operating and, with its targeted therapies and superb use of fast-moving science, personalised medicine has a key role to play.

The result of all the work undertaken by stakeholders in the methods outlined above have without doubt greatly assisted in opening the minds of policymakers to the great potential of this new model.

Of course, there are still many barriers to be overcome, but there can be little doubt that the emergence of personalised medicine has now found its way into both EU and Member State policymakers' mindsets and has already had a profound effect in key areas of recent policy and legislation.

This will become more and more the case, in the short-, medium- and long-term.



**Denis Horgan**  
EAPM Executive Director

# INTERVIEWS

## SECTION 1

MEMBERS OF THE EUROPEAN PARLIAMENT



Great!  
I see you  
have been  
shooting for  
the moon!

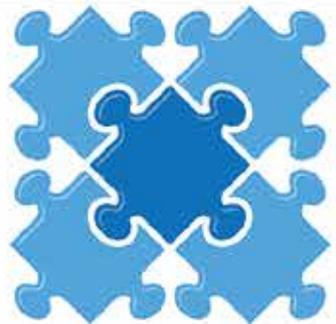
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# AI: A EUROPEAN STRATEGY FOR A CHANGING WORLD

**Born in Wels, Austria, Paul Rübiger has been a Member of the European Parliament since 1996. He is a member of the Austrian People's Party, which forms part of the European People's Party sitting in Brussels and Strasbourg.**

*Paul gets to grips with genetics*



Paul Rübiger, Member of the European Parliament

Paul, who sits on the Parliamentary committees on Budgets and ITRE (Industry, Research and Energy), graduated from Johannes Kepler University Linz, and is the author of *Entrepreneurship Needs Freedom: A Practical Demonstration of the European SME Legislation*. He also holds a Decoration of Honour for Services to the Republic of Austria.

EAPM is proud to say that Paul has supported our organisation since its formation, and has acted as a well-known advocate for personalised medicine and a healthier Europe in its broader sense. He has often hosted evenings on our behalf in the Parliament, and spoken at many Alliance events, including our conferences and pre-conference dinners, and at one point during our long association he addressed attendees on the subject of genomics for health. Paul said that research since the sequencing of the whole human genome “has greatly furthered understanding of the genome’s implications for health. These advances have been matched by a revolution in technology that has slashed the costs of sequencing and increased its availability”.

“The original \$3-billion cost for sequencing the first human genome would now buy a staggering one million, and the timescale has been slashed significantly.”

He added that: “Although it is happening slowly, genome sequencing is steadily being introduced into clinical care - improving diagnoses and care of patients with rare genetic diseases and impacting on cancer diagnosis and stratification of therapies.”

But he also acknowledged key challenges, which he named as the fact that test results must be delivered quickly, and data must be presented so as to allow relatively simple decision making by physicians.

He added that adapting sequencing to potentially life-saving clinical work needs much higher levels of sensitivity and specificity than is currently required for research.

Underlining his points, Paul said that: “Europe’s health systems need to adapt quickly to allow health genomics to benefit patients. As mentioned earlier, the cost of genome sequencing has fallen substantially and this is clearly one area that can support personalised medicine.

“(Europe needs) to shape the landscape for the successful implementation of genomics and related technologies in the healthcare arena.”

The Austrian MEP added that: “Overcoming the challenges facing us will ensure that, during the coming years, Europe can fully realise the potential of next-generation sequencing and its use in personalised medicine, thus improving healthcare and reducing costs.”

EAPM would like to sincerely thank Paul for his unceasing support for the Alliance and seemingly unstoppable belief in the potential of personalised medicine.

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### **EAPM’s executive director Denis Horgan (DH) again discusses aspects of artificial intelligence, this time with MEP Paul Rubig (PR).**

Paul Rubig is a Austrian Member of the European Parliament in the European People’s Party and he is a permanent member of the Committee on Industry, Research and Energy (ITRE) and of the Committee on Budget Control (BUDG).

**DH:** As far as you understand it, what is Europe’s strategy when it comes to artificial intelligence, or AI?

**PR:** There’s no doubt that AI is changing the world around us. Not least in healthcare where, for example, algorithms can help dermatologists make better diagnosis by detecting 95% of skin cancers by learning from large sets of medical images.

AI improves products, processes and business models in many sectors, and we need to be sure to harness it to full effect here in Europe, where we are often under-resourced in this field and have to compete with the US and China, who are throwing vast sums of money at AI.

Having taken all this on board, the European Commission published a European strategy last April. The Berlaymont put forward an approach that it says places people at the centre of the development of AI.

It also encourages the use of technology to tackle such issues as curing diseases, climate change and anticipating natural disasters. It also wants to use AI to make transport safer and improve cybersecurity.

**DH:** Is this all euro-centric?

**PR:** Pretty much, although some of the issues are clearly global. But the Commission says that its strategy supports an ethical, secure and cutting-edge AI made in Europe.

The executive adds that it plans build on Europe’s scientific and industrial strengths and is based on increasing public and private investments in AI, while preparing for socio-economic changes.

It also makes the point that coordination at European level is essential for success.

**DH:** You mention ‘coordination’. How do the Member States fit in?

**PR:** The Commission wants to work with Member States to maximise the impact of investments at EU and national levels, encourage synergies and cooperation across the EU, exchange best practices and define the way forward.

The goal of all this is to ensure that the EU as a whole can compete globally. The coordinated plan has been built on the declaration of cooperation on AI launched

last April at the Digital Day in Brussels. It was signed by all EU Member States plus Norway, and endorsed by the European Council in June of last year.

Between them, Member States and the Commission have identified a series of common actions to increase investments, pool data, foster talent and ensure trust.

**DH:** What are the priority areas?

**PR:** Mainly what they “call areas of public interest”. These include healthcare, transport and mobility, safety, security and energy. We can add to this list manufacturing and financial services.

The Commission has now put together a plan of actions which will run across the next two years while preparing the ground for the years to follow.

It attempts to coordinate national strategies across the bloc. So far, five Member States have adopted a national AI strategy with its own budget, and the Commission is encouraging all the others to do the same by the middle of this year.

As for 2020, Member States and the Commission are expected to agree on indicators to monitor AI uptake and its development in the EU.

**DH:** How are we doing on investment?

**PR:** Quite frankly, we’re behind. If we don’t have a big push in the AI arena we risk losing out on opportunities, losing a lot of clever people and being a consumer for solutions developed outside of the Union.

The Commission says that its strategy sets ‘ambitious, yet realistic, targets’. This includes a push to scale up private investment to reach a target of €20 billion annually over the next ten years. It sounds a lot, but it isn’t relatively speaking.

For its part, the Commission has increased investment in AI under the research and innovation framework programme to €1.5

billion in the period up to 2020. That’s a 70% increase compared to 2014-2017.

Meanwhile, the Commission has proposed that, under the next period from 2021 to 2027, the EU invests at least €1 billion each year in AI from the incoming Horizon Europe programme, as well as the Digital Europe programme.

And for their own part, Member States have acknowledged the need for ambition and an increase in national efforts. This should help leverage more private investments, the Commission says.

**DH:** Can regulators help?

**PR:** Yes. And one of the most important jobs they can do is work to eliminate obstacles caused by fragmented markets.

We all now that, these days, products and services are becoming increasingly interlinked and digitised. So it’s vital to avoid market fragmentation in areas such as artificial intelligence.

The Commission insists that ‘a real Single Market with an integral digital dimension’ will make it easier for businesses to scale up and trade across borders. They are correct, in my opinion, and it should help to secure investment down the line.

Overall, Member States and the Commission need to find ways to cooperate more with the private sector, by bringing firms and research organisations together to develop a common strategic research agenda in the AI field.

The goal is to create a new research and innovation partnership in respect of AI. With this in mind, the private sector is expected to commit to what the Commission describes as “specific and high investments” in AI.

**DH:** Where do Europe’s researchers fit in, assuming we can keep hold of them?

**PR:** Well, as part of the over-arching strategy, Member States and the Commission are looking to scale up national research capacities and create tighter networks of

European AI research centres of excellence. What we want ideally is cooperation among the best research teams in the EU. Working as a joint force should make tackling scientific and technological challenges in AI more efficient.

Research is one thing, of course, but bringing state-of-the-art AI applications to market means testing them in real-world environments. The 2016 Digitising European Industry strategy has allowed the Commission to support pilot schemes and experiments in lots of areas.

These include what we can call smart farming, smart cities and autonomous vehicles.

Of course, the Commission and Member States are learning lessons from such field experiments, and these will expand and grow.

**DH:** Any other initiatives ongoing?

**PR:** Yes. For a start, the Commission has set about adapting learning and training programmes and systems to better prepare society for the changes that AI is bringing and will bring in the future.

It turns out that pretty much every Member State is facing shortages of information and communications technology professionals, while researchers and start-ups often receive interest from outside the EU.

The bottom-line is that Member States need to exchange best practices on how, as the Commission put it, “to reinforce excellence and retain talented workers”, while also attracting talent to these shores.

Other aspects include developing a well-functioning data ecosystem built on trust, data availability and infrastructure.

**DH:** Finally, what is the impact on healthcare?

**PR:** Very promising, Denis.

For example, next year, using Horizon 2020, the Commission will support the development

of a common database of health images, which will initially be dedicated to the most common forms of cancer. It will use AI to improve diagnosis and treatment.

This is just one application, and there will be many more in the not-too-distant future.

**TARGETED TREATMENT  
IT'S IN OUR DNA**

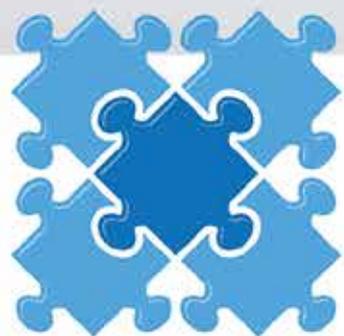
# Digital Skills for medical students?

Scalpel!

I have a computer mouse...  
To check your BIG data...



ComicHouse 50  
VdPOL





# ARTIFICIAL INTELLIGENCE AND NEW OPPORTUNITIES FOR EUROPE



Cristian Buşoi,  
Member of the  
European Parliament

## *Buşoi busy on boosting the best healthcare*

As a member of Romania's Partidul National Liberal party, and a Christian Democrat in the European Parliament since 2007, Cristian Silviu-Buşoi will be standing for re-election in the European election in May this year.

Since entering the EP, he has been busily involved with the ENVI Committee (Environment, Public Health and Food Safety) in Brussels and Strasbourg and is a much-welcomed regular at EAPM conferences and other events.

As a physician, Cristian obviously has a keen interest in healthcare in Europe and, since his re-election to the hemicycle in 2014, has been an active member of the STEPs group of MEPs that has worked alongside the Alliance since EAPM's formation ('STEPS' stands for Specialised Treatment for Europe's Patients.)

Cristian, whose home town is Drobeta Turnu-Severin, has consistently worked hard on behalf of patients across Europe and for the cause of personalised medicine. We, of course, wish him all the best as he aims to be part of the next legislature in Brussels, and earnestly hope to be working with him again in the coming years. A recent example of Cristian's work came on the back of Parliament's ENVI committee adopting 11 compromise amendments in respect of what's been called the European Social Fund Plus (ESF+). One of the compromises would boost funding for the health strand from the Commission's proposed €413 million to €473 million between 2021-2027.

As rapporteur, Cristian says he is against plans to put the health budget under the larger umbrella of ESF+, with ENVI noting that he "regrets" the withdrawal of health as a separate and robust programme, "finds unacceptable the proposed decrease of funding for health" and argues for increasing the budget to at least the same level as in the current Multiannual Financial Framework. Well done, Cristian!

In a recent interview with EAPM, Cristian spoke about access to healthcare technology, saying: "My colleague in Parliament, Soledad Cabezón Ruiz, was rapporteur for the ENVI committee on this topic and, as she said, we aim to improve access to health technology in the EU,

especially in terms of quality but also in choosing research projects according to medical needs, as well as added value for patients and public health systems.

“What Europe needs is a regulation on HTA to allow Member States to make the most reasonable choices for patients and for the public budget, and the regulation will help overcome disparities, reduce barriers to accessing innovative treatment, recognise the true value of new therapies, and improve the sustainability of national healthcare systems.

“Strengthening cooperation across countries will also provide better estimates of the medical and social value of new therapies and medicines.”

We thank Cristian for his sterling work in pushing for better patient access to the best treatments available and for his tireless promotion of personalised medicine. He is a true champion of the cause!

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**EAPM’s executive director Denis Horgan (DH) discusses the present and future of artificial intelligence in Europe with Romanian MEP Cristian-Silviu Buşoi (CB). Cristian, who is a trained physician, has been a Member of the European Parliament since 2007 and will stand for election again in May. He is a substitute on the Environment, Public Health and Food Safety committee, known as ENVI, and a member of the EPP group in Parliament.**

**DH:** Cristian, can we please start with a brief description of artificial intelligence?

**CB:** Of course. Artificial intelligence, or AI, covers systems that display intelligent behaviour by analysing their environment and then taking actions to achieve specific goals. This is done with some degree of autonomy. Examples around us include using a virtual assistant, although I have real ones, to organise things, self-driving vehicles, and suggestions from your phone in respect of maybe a restaurant you might enjoy, a song you might like, plus voice and face recognition and so on. Advanced robots can use AI, as can ‘internet of things’ apps, drones and, of course, AI can be used in healthcare.

**DH:** Can you elaborate on the latter instance, please?

**CB:** Well, for example, I recently read that in Denmark AI helps emergency services to diagnose a cardiac arrest based only on the caller’s voice. That’s pretty incredible. Meanwhile, Austrian radiologists use the technology to better assist the detection of tumours by comparing x-rays with other medical data, all in an instant.

**DH:** You mentioned data. How important is data in respect of AI?

**CB:** Very important indeed. A lot of the AI technologies rely on data in order to function better. Once performance is up to a high level they can help to improve and automate decision making in their particular domain. Here in Europe we have a vast amount of data, a real wealth of information that can be pushed towards AI systems in a variety of fields, including healthcare. In fact, the European Commission is taking action to make data sharing easier and to open up more data for re-use. This includes research and health data, under strict conditions, of course.

**DH:** OK, so how well is Europe doing in terms of AI? Are we in the forefront?

**CB:** The field is already a large one and is predicted to grow phenomenally quickly in the next decade, much as personalised medicine is doing, in fact.

AI is going to change our world, it really is. The promise has nowhere near been fulfilled yet and new applications will come along one-after-the-other. Therefore, the opportunities for Europe are huge. But we need a solid framework as the competition globally is, and will be, just as huge. In this sense, the EU needs to be better prepared if we are to keep up, let alone take a lead, in the context of AI and its promise. A coordinated approach is certainly required, as we definitely already have resources such as brilliant researchers, excellent laboratories, forward-looking entrepreneurs, and strength in robotics.

Industry-wise, we are strong in the realm of healthcare, as well as in other fields, and we should make certain that we are ahead of the game when it comes to utilising AI.

**DH:** What's the feeling across Member States?

**CB:** I'm very happy to say that Member States have put AI at the top of their agendas. As recently as April of 2018, 24 Member States plus Norway agreed to work together in respect of AI.

The goal is to be as competitive as possible, and that can only really happen with support for research and innovation geared towards developing the next generation of AI technologies.

Now that the General Data Protection Regulation is in force, hopefully trust will increase, and with it cooperation. Sure, there will be new ethical and legal questions, as we find with any leaps in technology, so we obviously need appropriate frameworks in place. The EU has recognised this.

Overall, the future for AI and Europe moving forward together looks bright. We're in good shape but we have to stay that way. Parliament, as ever, will play its part.

**DH:** What has the Commission said in the

context of AI development?

**CB:** Back in May 2017, not all that long ago, the Commission published a mid-term review of the Digital Single Market strategy. This review made a point of the importance of building on Europe's scientific and industrial strengths in attempts to be global leaders in the development of AI technologies, platforms, and applications.

A few months later, in October of that year, the European Council highlighted that the EU needs a sense of urgency when it addresses emerging trends such as AI, within high levels of data protection, digital rights and ethical standards. The Council invited the Commission "to put forward a European approach to artificial intelligence".

For our own part, the European Parliament made wide-ranging recommendations on civil law rules on robotics.

On top of this, the European Economic and Social Committee has also issued an opinion on the subject of AI.

**DH:** So what actually are the concrete aims in respect of AI?

**CB:** I refer here to its own Communication... The Commission has said its goals are to boost the EU's technological and industrial capacity and AI uptake across the economy, both by the private and public sectors. It also intends that Europe prepares for socio-economic changes brought about by AI by encouraging the modernisation of education and training systems and, as I mentioned, it pledges to ensure an appropriate ethical and legal framework, based on EU values and in line with the Union's Charter of Fundamental Rights.

**DH:** In practical terms, what needs to be done?

**CB:** A joining of forces and a coordinated plan across the EU. Key to the best results will be, as the Commission has rightly said,

maximising the impact of investments at EU and national levels, encouraging synergies and cooperation across, exchanging best practices and collectively defining the way forward so that the EU as a whole can compete globally.

**DH:** With the commitment of 24 Member States that you mentioned, and the Commission's stated goals in the field, can we assume that the EU is on the right track in its handling of AI's potential?

**CB:** Of course, it's early days, and things are moving so quickly... But I think so. Most of the world's developed economies recognise that AI is a game changer and EU Member States are no different. This is just as well as the US and China are throwing huge amounts of money and other resources into AI, as are Japan and Canada. The problem is that, cash-wise, we are behind. The latest figures I have show that private investment in Europe in this field came to a maximum €3.2 billion in 2016, while Asia topped out at €9.7 billion and North America weighed-in with an amount that may have been as high as €18.6 billion. So we need to up our game and work hard to, as the Commission puts it, create an environment that stimulates investments and uses public funding to leverage private investments.

We've already got a world-leading AI research community, but we need to ensure that the take-up of AI technology goes across the whole economy.

It's a big challenge, but it's one that I believe we can, and must, meet. We need to use our own natural intelligence and do the job properly in terms of the artificial kind.

Quaestor on a quest for better healthcare

# **PUTTING THE PERSON INTO PERSONALISED MEDICINE**

# Scepticism towards personalized medicine in the Stone Age...



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# DATA:

LET IT FLOW, LET IT FLOW, LET IT FLOW...



Sean Kelly, Member of the European Parliament

*Kelly's eye on healthcare and a solution to the Brexit 'backstop'*

Ireland's Seán Kelly has served as a Member of the European Parliament since 2009.

Killarney-born Seán is a member of Fine Gael, which is part of the European People's Party. He sits on the Industry, Research and Energy committee (ITRE).

As well as taking a keen interest in healthcare, as an Irishman Seán is obviously concerned by the prospect of a no deal Brexit, and the threat that may pose to the currently open border on the island of Ireland.

In a January 2019 debate, Seán told colleagues in the hemicycle that everyone can sense the unity of the EU27, and that that is to be admired. He thanked (EU chief negotiator) Michel Barnier, "who did a tremendous job, and to everybody involved. Ireland would like to express its gratitude for that".

Seán took issue with a comment made by Arlene Foster the day before (Foster is leader of the ten-strong Northern Irish DUP group of MPs currently propping up Theresa May's government in the UK). She had said: "There is no need for the backstop, as we never had a hard border."

The MEP's response to that was unequivocal, and he told fellow MEPs in Strasbourg: "My goodness! Try telling that to those who were killed when they were crossing the border, who were subjected to searches by British soldiers, who saw the watchtowers, who were victims of the violence and, indeed, terrorist acts.

"I must say that this is not helpful, and because of that violence we had the Good Friday Agreement. And, in fairness, and to give credit to Theresa May, Michel Barnier and the EU as a whole, they did everything in the Withdrawal Agreement to ensure that the Good Friday

Agreement would be observed in all its parts and that peace would continue on the island of Ireland.”

Seán continued: “The big worry now for most people is that there will be no deal”, he said, “(and) that the United Kingdom will crash out of the European Union, and preparations are in place in case that is the outcome”.

“But I think it’s important for the United Kingdom to make a decision that that is not what it wants. I have no doubt that the good people of the United Kingdom do not want that scenario, and if given the opportunity they would say so.”

He suggested consulting those who “actually voted for Brexit in the first place – the British people – and ask them ‘Is this really what you want?’. I think they will say emphatically ‘No’”. Like many of his fellow countrymen and women, Seán is clearly deeply passionate on certain topics. Clearly Brexit is one of them, but so too is bettering the healthcare opportunities for citizens across the EU.

EAPM would like to thank Seán for all the help and support he has given to the Alliance down the years.

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**This next interview sees EAPM’s executive director Denis Horgan (DH) chat to Sean Kelly MEP, on data flows, the potential and the reality, and how Big Data can have an impact on personalised medicine.**

**Sean Kelly is a member of the European Parliament since 2009 and he sits on the Industry, Research and Energy (ITRE) Committee, the International Trade Committee and the Fisheries Committee.**

**Kelly was the ITRE rapporteur for the General Data Protection Regulation and he was voted 2014 MEP of the year in the category of Digital Agenda for this work on data protection.**

**DH:** Big Data is everywhere, and the EU is trying its best to regulate its flow for privacy and ethical reasons while, at the same time, trying to ensure that it can be freed-up for the public benefit, not least in the arena of health.

First thoughts?

**SK:** Well, let’s look at the much-vaunted idea of the data-driven economy here in Europe for a start.

Data has been referred to as ‘the fuel of the future’ and that’s not a bad metaphor. But it’s actually the fuel of the present as there is so much out there already, albeit we can find more optimal ways of using it while safeguarding privacy, which has not always been the case, even in the wake of the General Data Protection Regulation.

Lest we forget, there have been some very high-profile misuses, or at the very least tangible instances of negligence, on the part of some data-reliant companies that we all know about.

Anyway, as the Commission and the rest of us have noted, the generation, collection, processing and use of data is transforming our economy.

Data-driven technologies have the potential to enhance productivity and competitiveness, and benefit citizens in areas such as

education, employment and healthcare. Healthcare is our topic here, so in that arena there are opportunities to develop further machine-learning tools for early disease detection, coordinate the collection and sharing of health data for improved treatment, and beef-up and then finesse applications of the so-called Internet of Things.

The trick is, of course, under proper and robust privacy and ethical rules, to make sure that citizens in all Member States grasp the benefits and make best use of them.

A prerequisite of this is to ensure that data flows as freely as possible across borders and between sectors.

**DH:** We are hearing a lot about 'open data'. What is that, exactly?

**SK:** OK, I'll try to define that. You're making me work hard, here, Denis...

From what I understand, our friends and colleagues in the Berlaymont say that the ideal open dataset has properties that mean it is non-personal in content, includes public and commercial data, and is of use to manufacturing and service industries. This open data can be accessed with insignificant charges or it may be free, often as it is already in the public domain.

Meanwhile, regarding intellectual property rights and confidentiality, there are either no limits or negligible restrictions on the access, copying, processing, addition, transfer, exploitation, alteration, reformatting and redistribution of the whole dataset.

No part is reserved or precluded from processing, and it may be used in any way for commercial gain by the new user.

And from an accessibility point of view, a wide range of users can access the whole open dataset, with no preferential treatment for any user and no dataset parts reserved for preferred users.

On top of this the datasets are ideally in a machine-readable form allowing processing by computer, even if the data is not in a well-known format.

That's all about as 'open' as you can get. The concept certainly has possibilities in terms of eHealth and education, just for a start.

**DH:** Open data aside, there are of course issues with ownership in the case of most data...

**SK:** Indeed. Pretty much any discussion on the use of data begins with who owns it.

This obviously depends on what the data is, how it was generated, what devices were used and where it came from.

There's plenty of discussion and finer points but, in the main, there are four categories of data, which vary by what we can call the owner.

These owners are the State which, in the majority of cases, is the largest producer and owner of data. Then there's the citizen who generates and, and at least in theory, owns his or her data - although 'local' rules apply in different Member States.

Then there's the data producing and moving companies, which include internet service providers, telecom and utility companies, retail chains, banks, financial services and insurance firms, and what we can call third-party aggregators.

This last grouping includes credit ratings agencies, as well as internet companies such as Google, Amazon, Apple, Facebook and Microsoft, whose collected amounts of data make the mind boggle.

On the ownership point, there's a big argument that says, not least in medical terms, that patients should be the owners of their own medical data and be able to choose how, when and where it is used, if at all. I say 'if at all', although it has been shown that most patients are happy to allow their

personal data to be used for research that will benefit future patients, albeit under robust rules governing ethics and privacy.

**DH:** Is there any way of putting a value on all this data?

**SK:** Information is clearly an asset for lots of organisations, and not just commercial ones. But it suffers somewhat from being intangible and you won't see it appear on a balance sheet. Not yet, anyway.

The problem with this situation is that it is more than likely that the widespread sharing, or trading, of open data will not reach its full potential unless we find a way to measure the value of datasets and other assets based on gathered information.

**DH:** So how do you see data flowing in the future?

**SK:** Well, there are many scenarios. Data-sharing between research organisations dealing in healthcare. Perhaps a breaking down of some barriers that exist within silo mentalities and, of course, commercial mentalities.

It may sound odd, but there is the possibility of an increase in open sharing by commercial data owners. This is sometimes referred to as data philanthropy.

The theory runs that those who do this may see some value in opening their databases to further processing.

Examples could be banking, mobile telecoms and information services, according to the Commission. But so far, perhaps not surprisingly, there are not too many examples of commercial enterprises sharing private data within the definition of open data.

On the other hand, it appears that some sectors see a strategic interest in having

their data embedded in as many combined datasets applications as possible, as a form of advertising. That's a Commission observation and they could well be right.

But, lets be honest, the 'big boys' who have collected and stored massive amounts of data are not generally the ones to engage in open data flows!

**DH:** So, Big Data in health?

**SK:** Well, in general terms it has been estimated that Big Data could save the public sector €100 billion in 'operational efficiency improvements'. That's just not in health-related areas, but it gives an idea of the potential, here.

The fact is that increases in computing power and new technologies have really brought down the price of using data in healthcare.

The technology is incredible. These days 'wearables' and more are already modernising healthcare as tracking activity, while remote monitoring and reminders to encourage medicine adherence help to bring about better healthcare outcomes.

This means greater independence for the patient, a better quality of life and much-lower hospital bills. And here's the kicker on adherence - it's been estimated that reducing non-adherence in medicines could save €125 billion annually and reduce premature deaths by 200,000 each year.

In Europe. Just in Europe. That's amazing.

**DH:** Not a bad start. Anything else?

**SK:** Oh, plenty Denis...

I know that EAPM has already pointed out that making effective use of Big Data will bring about improvements in efficiency, improvements in decision making, and smarter investment.

Health-wise, and particularly with regard to your specific field of personalised medicine, Big Data represents the vast and continuously growing amount of health information and its usage to drive innovation in translational research and health outcomes tailored to the individual.

I don't need to tell you, then, that using these data to first understand the cause of disease, healthcare professionals can then develop new drugs and therapies to find the cure, as well as other health interventions targeting the individual.

As we know, the personalised, individual approach requires advanced technologies and processes to collect, manage and analyse the information and, even more importantly, to contextualise it, integrate it, interpret it and provide rapid and precise decision support in a clinical and public health context.

But first of all we need that information, the data flows if you will.

**DH:** So Big Data is a massive asset already and will be down the line...

**SK:** Oh, yes. There's probably nothing quite as massive, in healthcare and beyond.

Specifically, focusing here on a relatively new development, the ability to cost-effectively sequence a whole genome and the value this would bring to a patient's care will soon bring genomic data into routine practice and its integration into electronic health records.

(We could do with that process being speeded up, by the way, although the Commission is on it as we speak.)

In the context that I've just mentioned, researchers would potentially be able to access millions of genetic markers. In turn this would accelerate science towards better understating between diseases and specific

patients.

The potential, yet to be fully realised, for knowledge coming from these data to be used to improve medicine in many areas, is significant.

But effective data interpretation requires the rapid involvement of experts and organisations everywhere. The hurdles of healthcare data fragmentation, representation and organisational boundaries will need to be tackled for innovation in the field to succeed.

Also, the massive quantities of data involved from hundreds of different sources means that, to get the best out of it, networked environments will need to work together. As ever, it all comes down to cooperation. In this case, through sharing.

Data flows need to be optimal and, that way, these astonishingly large datasets that we potentially have access to can not only inform the future, but even design that future.

As opportunities go, this is about as big as it gets.

**SPECIALISED TREATMENTS  
FOR EUROPE'S PATIENTS**



European Alliance for  
Personalised Medicine



# NEW HORIZONS FOR RESEARCH IN EUROPE

Soledad Cabezon Ruiz,  
Member of the European  
Parliament



## *Soledad solid on HTA and healthcare*

As a member of the Spanish Socialist Workers' Party, and Member of the European Parliament (Group of the Progressive Alliance of Socialists and Democrats) since 2014, Soledad has a degree in medicine and surgery, which clearly underlines her keen interest in healthcare and getting the best for the EU's patients, which has been evident during a pretty high-profile first term in the hemicycle.

Recently, she was rapporteur for the ENVI committee on the ongoing issue of health technology assessment and, as she said towards the end of 2018, the goals are to improve access to health technology in the EU, especially in terms of quality but also in choosing research projects according to medical needs, plus as added value for patients and public health systems.

As ever, there were creases to iron out on the hot topic of HTA, but almost all of the compromises discussed under Soledad's watch were adopted.

At the time she said: "There is clearly an added value for patients and for public health systems in establishing an EU-wide system. Health is a fundamental right, and we must do our utmost not to let the market logic prevail, so we ask the Commission to propose a regulation on Health Technologies Assessment."

"In the last decade," she added, "the price of anti-cancer drugs has increased by up to 10 times more than their effectiveness as treatments....studies show that based on an average of five years' monitoring, only 14-15% of the drugs improve survival rates.

"In addition, a very high percentage of new medicinal products brought onto the European market offer no advantage over existing products".

Soledad also said that: "The need for more evidence on medical devices led 20 member states and Norway to introduce clinical assessment schemes, adopt guidelines and carry out public consultation procedures at an early stage. It is a shame that the EU is lagging behind."

"A regulation is needed to make global regulation possible, to clear the way for the right balance to be struck between all parties and interests, with the focus on the patient, to

guarantee access to medicines as well as the sustainability of healthcare systems, and to foster high-quality research and development.

Since the launch of the Commission's HTA proposal in January of last year, the issue of more EU-wide cooperation in HTA has seen continuous engagement on the topic between EAPM and MEPs, including Soledad.

This will continue going forward. Indeed, EAPM has hosted meetings on the topic and we know that Soledad's work will continue down the line, as will ours.

In the meantime, we sincerely thank and admire her for the excellent efforts she has made in pushing for better patient access to the best treatments available.

Soledad is a true patients' champion and we are delighted to be working alongside her.

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**For this interview EAPM's executive director Denis Horgan (DH) discusses the European Commission's Horizon Europe programme, which is set to take over from Horizon 2020, with MEP Soledad Cabezon Ruiz (SC). Soledad Cabezon has been a Member of the European Parliament since 2014. Since 2015, she has been serving on the Committee on the Environment, Public Health and Food Safety (ENVI). She is the shadow rapporteur of the decision specific HUE and she was the rapporteur of mid term review for Horizon2020.**

**DH:** First of all, could you give us an overview of Horizon Europe in respect of research and innovation, please?

**SC:** OK. Every seven years, the EU decides its long-term budget. Last summer the European Commission put forward its proposals for Horizon Europe, which is due to kick in on 1 January, 2021, as Horizon 2020 ends. It will be the ninth such framework and will incorporate what the Berlaymont has called 'policy missions' in order to ensure the effectiveness of research and innovation funding by pursuing clearly defined targets.

The programme will run through the EU's next financial period, from 2021 to 2027, and a proposed €100 billion is on the table

to finance science. The vast majority, that's about €94 billion in current prices, would be allocated to the Horizon Europe framework programme.

The Commission says the main aims are to strengthen science and technology, foster industrial competitiveness, and implement sustainable development goals.

Also in the pipeline are new features such as the European Innovation Council, whose mission is to promote innovation and solve the gap referred as valley of death.

Meanwhile, the programme is looking to define operational objectives and activities, especially for those 'missions', the European Research Council, and more.

**DH:** What do we know about the proposed new features that you mention?

**SC:** Let's take the European Innovation Council first... The Commission says that his new platform would become a one-stop shop to support high-risk, market-creating innovation projects by bringing promising ideas from the laboratory to real-world application.

This would be done through direct financial support provided by two main funding

instruments, which are called 'Pathfinder' and 'Accelerator.'

Meanwhile, the EU-wide missions would be conducted to promote research and innovation outcomes, for example in the fight against cancer.

The new partnerships would be open to all types of stakeholders and work under a time limit, while a plan for 'open science' would become the modus operandi of the whole Horizon Europe programme. This means open access to all publications, data, and to research data management plans.

**DH:** Does the Horizon Europe programme offer any improvements on its predecessor?

**SC:** The Commission says so. It acknowledges criticisms of Horizon 2020, after stakeholders highlighted an uneven distribution of the framework programme funding across the EU.

Stakeholders also asked for a greater interlinking of the shared, multi-level governance between the EU, Member States and Europe's regions.

Not surprisingly, the complex funding landscape got a bit of a bashing.

The Commission tells us that, between January and March last year, it ran a public consultation on future EU funds in investment, research and innovation, SMEs, and the single market.

It had more than 4,000 stakeholder submissions.

According to most of them, the main obstacles to Horizon 2020 achieving its objectives were very complex procedures, a high administrative burden, a lack of flexibility to react to unforeseen circumstances, insufficient synergies between other EU

programmes and funds, and the difficulty of combining EU action with other public interventions and private finance.

On the plus side, it seems that most stakeholders expressed satisfaction with the existing three-pillar structure of Horizon 2020 and merely asked for minor refinements, such as a better linkages between pillars for better coverage of the whole knowledge chain.

Interestingly, these stakeholders also suggested boosting funding for the European Research Council, which is widely popular.

**DH:** What is the view from Parliament on the whole package or, if you prefer, parts of it?

**SC:** It's fair to say that certain MEPs on the ENVI and Research and Industry committees have called for more money for research and development to be allocated than originally proposed.

As recently as November, the Research and Industry committee called for more ambitious public investments to address the burden of poverty-related and neglected tropical diseases, such as HIV and AIDS, tuberculosis, malaria, and so on.

The EP called for an increase in the overall research budget up to €120 billion, a call which was backed by Parliament in Strasbourg in mid-December, but which is seeing resistance from several Member States.

**DH:** So where does that leave us?

**SC:** With probably another year of to-ing and fro-ing, to be honest, Denis. Although the Rapporteur, is of the opinion that Member States will come around. He pointed out that the ultimate goal is to reduce the gap between the US and EU in research and innovation.

On the other hand the EP supports the idea of a larger research budget, So it's all up in the air.

**DH:** Is Brexit an issue, here?

**SC:** It could well be. To put it in some context, an amendment during the December plenary to guarantee that UK scientists would still be able to participate in EU-funded research failed.

The HUE rapporteur, for one, said that the question needed to be settled by the UK and EU, and not as part of the Horizon Europe legislation.

But there is certainly an argument that Europe needs Britain at much as Britain needs Europe in the fields of technology, science and research.

We recognize the value of the British contribution to science and that it would be necessary to find ways of collaboration ... if not, the big loser would be UK ...

The jury is still out and nothing has been decided. It's all very unfortunate and there will be implications, of course.

**DH:** OK, once the budget is finally decided, what are the implications for, say, translational research and healthcare down the line?

**SC:** Well, let's start with a bit of basic background. European researchers have been at the forefront of major scientific healthcare discoveries in areas such as cancer, cardiovascular disease, genetic disorders, and infectious disease.

But we need to figure out how best to translate this knowledge and expertise into medical advances that improve outcomes and enhance wellbeing.

Obviously, translational research is a key

enabler of the EU's research effort and allows discovery science to be converted into new diagnostics, treatments, products and approaches that benefit society.

We need a coordinated European research agenda that enables efficient and effective translation of scientific innovation, underpinning practice-changing clinical advances for patients.

**DH:** I know that you have an interest in the concept of personalised medicine and acknowledge its potential. What does this new form of treating patients need from a research and innovation perspective?

**SC:** Personalised medicine's potential is awesome, but uptake is slower than it should and could be. It needs to be embedded into the EU's healthcare systems to allow professionals to give the right treatment to the right patient at the right time.

While Europe undoubtedly continues to produce excellent science that provides an increasing insight into the role of biology in health and disease, the ability to translate these research discoveries into new approaches that will benefit the patient are undermined by significant gaps in the knowledge base in Europe.

Those, such as yourself, who strongly advocate personalised medicine, have persuaded me that fragmentation of research efforts, the pressing need for comprehensive stakeholder engagement and the lack of a clearly defined roadmap for translation of research discoveries for clinical application are hampering implementation.

On top of this, having mentioned stakeholders, it is clear that the participation of patients and patient advocates down the line is crucial to the ultimate success of personalised medicine.

**DH:** Can you elaborate on that latter point, please?

**SC:** Of course. Early engagement with patients and patient advocacy groups is a key requirement for the development of personalised medicine. But there are gaps in the literacy of patients and their representatives.

More information on personalised medicine approaches needs to be out there.

**DH:** Just for the patients and their groups, or for others, too?

**SC:** For everyone. Awareness raising across the board - and I include the media, politicians, policymakers and more - has to be coupled with ongoing education for healthcare professionals in order that they are up-to-speed with exciting new methods.

They are the front line, and will have to get to grips with complex issues thrown up by fast-moving new science.

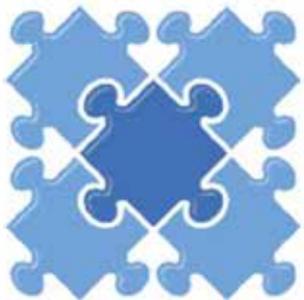
I know that you at EAPM have held several Summer and Winter Schools to help to address the knowledge gap, but we need much more of it and we need it on an EU-wide scale.

To summarise, research and innovation in Europe is brilliant, but it's not much use if we can't make the most of it and put it into practice in the most optimal way.

**BETTER HEALTH  
MEANS MORE WEALTH**

HOW IS THAT  
IMPLEMENTATION  
OF MODERN TOOLS  
COMING ?

"MODERN" ?



European Alliance for  
Personalised Medicine

# RESEARCH AND WHERE IT STANDS. *AN MEP'S VIEW...*



Marisa Matias, Member of  
the European Parliament

**The EU's interest in innovation and research began well before the financial crisis of 2008, although those events injected greater urgency into policy development.**

**The 2000 Lisbon Strategy's goal was to make Europe the most competitive and dynamic knowledge-based economy in the world. Stimulating and encouraging innovation and research are viewed as key drivers to economic growth in what is now a much more competitive external world than before. Bringing together all EU research and innovation funding within a single framework should ensure greater simplicity and efficiency for all involved in addressing research interests.**

**Well, that's the theory...**

Covering aspects of personalised medicine, EAPM's executive director Denis Horgan has been conducting a series of interviews. Here he speaks to Portuguese MEP Marisa Matias, who currently integrates the Economic and Monetary Affairs and Industry, Research and Energy Committees, about research, Horizon Europe and more.



**DH:** Marisa, Horizon Europe is an ambitious €100 billion research and innovation programme that will succeed Horizon 2020. Can you tell us more about it?

**MM:** OK, Horizon Europe will incorporate policy missions to ensure the effectiveness of research and innovation funding by pursuing clearly defined targets. The Commission talked to policy experts in order to develop studies, case studies and reports on how a mission-oriented policy approach will work. Hopefully it will provide coordination to close research gaps and stimulate innovation. Regarding these gaps, there are some chasms that need to be bridged in EU medical research funding between Commission programmes and Member State and Commission programmes. The vision of a knowledge-based economy is one of its core components, although this has not really happened over the past decade, despite the best efforts of pretty-much everyone. Also, there's still a gap between the western Member States and others which means inequalities in both the funding and the amount of research being undertaken. There needs to be reform, not least because SMEs and academic institutions often don't enter programmes because the submissions

process to access EU research budgets is complex, and it's also very costly. To make matters worse, there's a lack of what we call technology transfer professionals. These people combine an understanding of science with business skills, which in turn supports the research-to-market process. The bottom line, Denis, is that there is currently an acute shortage of private sector capital, especially in the current economic climate, available for research of all types, and this includes SME medical research. My fellow Parliamentarian Ness Childers has said that we need programmes to attract non-EU researchers to EU-institutions and also encourage Europe's citizens working outside of the EU to come 'home'. I agree with that observation as well as the need to establish favourable regulatory mechanisms for venture capital funds to invest long-term in healthcare R&D.

**DH:** You, yourself, published a paper on research and its funding in the EU. Tell us a little about that...

**MM:** Well, my paper spoke about a contradictory impulse in attempting to develop a coordinating strategy that will drive, concentrate and ensure the efficient management of resources towards high-performing institutions and one that seeks to reduce inequalities between Member States and their institutions by attempting to ensure a more equitable distribution of research resources and output between them. When I say 'institutions' I mean academic, national research promoting bodies, other public bodies and SMEs. The economic crisis exacerbated this problem because resources became scarce and economic growth difficult. I said at the time, and we were still under the cosh from that economic crisis, that if we decide that the pursuit of innovation is to be the number-one goal, then priority should be given to ensuring the best integration of links between science and business.

On top of this, there must be funding mechanisms to ensure the translation of technical advances into commercial successes.

Let's be clear, scientific research and its knowledge output is the foundation upon which activity to secure the objectives of an innovation strategy must be built.

Encouraging increases in technologically based start-up companies, supporting existing research focused SMEs, promoting the capacity of established companies to innovate, and encouraging the emergence of new business sectors based on new technologies, are all essential.

**DH:** Will this solve the issue totally?

**MM:** Unfortunately, much as we need it, more research doesn't necessarily lead to more innovation. Innovation can often be opportunistic or lack resources to get to market.

**DH:** Finally, specific to healthcare, your Parliamentary colleagues in the ENVI committee have adopted 11 compromise amendments in respect of what's been called the European Social Fund Plus.

**MM:** Yes, one of the compromises would boost funding for the health strand from the Commission's proposed €413 million to €473 million between 2021-2027.

ENVI's rapporteur in this case, Cristian-Silviu Buşoi, who has of course been a long-time supporter of EAPM and its goals, has said he's against plans to put the health budget under the larger umbrella of ESF+.

The minutes of a recent meeting ENVI noted that Cristian regrets the withdrawal of health as a separate and robust programme. He also said he finds the proposed decrease of funding for health unacceptable, and argues for increasing the budget to at least the same level as in the current Multi-annual Financial Framework.

I have to say that I agree with him.

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IS AN INVESTMENT, NOT  
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# PUBLIC HEALTH: THEN, NOW AND TOMORROW



Alojz Peterle, Member of the European Parliament

**This next interview sees EAPM's executive director Denis Horgan (DH) chat to Slovenian MEP Alojz Peterle (AP) on various aspects of public health.**

**With a vast majority of citizens believing that the EU should do more in this arena, it's sure to be a top topic ahead of the Parliamentary elections this coming May. During his three terms Alojz Peterle has been a member of the EPP group and is a founder of the MEPs Against Cancer (MAC) Group.**

**DH:** Given that this has been your third term in Brussels and Strasbourg, there must have been some big issues grabbing your attention, not least public health now and into the future. Please give us an overview.

**AP:** Public health is obviously a big deal and, given the challenges the whole of the EU faces, it deserves a high profile and a lot of focus. My country Slovenia, like all other Member States, has its own competence in health and has the same issues - such as an ageing population, increased comorbidity and chronic disease, and a lack of cash in the wake of this, plus a fear that health systems everywhere will become unsustainable if we don't act fast and use our limited resources more smartly.

As I mentioned, and as you know, Member States have competency in the main, but the EU has stepped up to the plate in certain areas of healthcare. It's a fact that most citizens want more EU action in this area, and most support what action the EU takes as a whole. Looking back over recent years we've had EU regulations covering clinical trials, IVDs, cross-border healthcare data and now we had the whole health technology

assessment debate with calls for mandatory joint action to cut down on duplication, up efficiency levels and share more and more important knowledge.

**DH:** EU health policy, where applicable, aims to foster good health, protect citizens from health threats and support dynamic health systems. What do you see as the challenges on a Europe-wide scale?

**AP:** Oh, where to start? As I've touched upon earlier, the obvious challenges include tackling the health needs of an ageing population and reducing the incidence of preventable chronic diseases. Going on with Commission statements, since 2014 steps forward have been made in a number of areas, including antimicrobial resistance, childhood obesity, health systems, medical devices and vaccination. Now we have the 2021-2027 multi-annual financial framework being discussed, with discussions about how much cash should be earmarked for research in the healthcare arena, a stand-alone health program that links to the European Pillar of Social Rights, and issues over equal access to the best healthcare, regardless of the particular geographical location and personal resources of the citizen.

**DH:** So how do you see the EU's main role in healthcare?

**AP:** Well, maybe it's not how I see it but as the citizenry sees it, and how the Commission has to see it as a reaction to that. The EU executive in the Berlaymont will tell you that the European Union's main role in health and social policies is to support the activities of the Member States, in order to assist them in achieving shared objectives, and to encourage cooperation across countries. The latter is something that is desperately needed, of course. The EU's health policy has been designed to focus on particular strategic objectives, which include

fostering good health, preventing diseases and promoting healthy lifestyles. This it does by addressing risk factors such as smoking, drinking, unhealthy diet and physical inactivity, as well as drug-related health damage and environmental risks, with special attention given to keeping people healthy into old age. To be honest, it could do better in every instance. We all know that, but there is no argument that says it isn't working hard. It has to, as do Member States. Health in these current times is among our biggest challenges. I am convinced that our starting point in all health policies should be the prevention. If we want results we first need a political commitment to prioritise prevention. Prevention has long been a political slogan, but not a targeted policy yet with clear economic indication. Promoting health and prevention are proven cost effective measures. Political decision makers who sincerely care about their national health budgets would be surprised how much reserve we still have in this area. We have a Commissioner for health but why not having a Commissioner for prevention as well!

**DH:** So what has Parliament done to help in your time here?

**AP:** Plenty, I'm happy to say. For example, in last mandate, since mid-2014, issues have been highlighted and results achieved in a number of areas, some of which we've mentioned, and I'll list a few of them briefly. Access to medicines is a big one, of course. Timely and affordable patient access to innovative, safe, effective and quality medicines was key to the June 2016 Council conclusions on strengthening the balance between the authorisation of new medicines and innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicines in the EU. For our part, Parliament's March 2017 resolution on options for improving access to medicines focused on the pharmaceutical market, competition, pricing

and transparency, EU cooperation, intellectual property, and research and development.

On European Reference Networks, or ERNs, in the area of complex or rare diseases, the EU has helped to pool scarce resources, currently scattered across Member States, by setting up the ERNs. These are virtual networks connecting healthcare providers throughout Europe. The aim is to bring together expertise and to maximise synergies between Member States for improved diagnosis and treatment of such diseases.

Around 25 ERNs have been established since March 2017, including 300 hospitals from 26 EU countries. Also, regarding medical devices, in April 2017, Parliament and the Council adopted two new regulations, one on medical devices and another on in vitro diagnostic medical devices, to modernise the regulatory framework and enhance patient safety. They contain, respectively, stricter rules to ensure that medical devices are traceable and comply with EU patient safety requirements, and information and ethical requirements for diagnostic medical devices. The bottom line is that Parliament is never far away from working hard to move the agenda forward, always with the citizen in mind.

**DH:** This is all important stuff that you mention. So what about remaining challenges and the future?

**AP:** There are many challenges remaining and I won't pretend that there are not. These include tackling the specific health needs of an ageing population and the increasing incidence of certain diseases, including Alzheimer's, as people get older. In that context, and beyond, we have to adapt to demographic changes and a growing demand for care with health system reforms that guarantee sustainability and universal access to high-quality care. Crucial now and down the line is reducing the incidence of preventable diseases, such as cancer, heart disease, respiratory, mental and other

chronic diseases. Also of vital importance is getting rid of the many health inequalities in terms of the differences in health and healthcare that exist especially between and also within different EU countries. The iron curtain between East and West still has to be addressed in that sense with much stronger ambitions. I could go on forever, but these are big issues as you know.

**DH:** And what's the potential for the future - the next Parliamentary term and beyond?

**AP:** Well, there are a few possible initiatives being considered on an EU-wide basis, taking into account Member State competence, of course. The key ones for us in this conversation are access to medicines, in which encouragement of broader and deeper EU-level coordination on the accessibility of medicines, especially high-cost innovative ones, is likely to continue to take centre stage. I saw not so long ago, also, that an expert panel on effective ways of investing in health, which provides the Commission with independent advice to specific mandates, has issued an opinion on innovative payment models for high-cost innovative medicines, in which it sees an opportunity for setting up a European learning community in the area of payment models. That would be a positive step, for sure. And the Commission thinks, and I would like to see this backed by my MEP colleagues, that the European Reference Network model in cross-border healthcare for rare diseases could be widened to other areas. To elaborate on that, the expert panel I just mentioned has suggested that there is potential to adapt the scope of the European Reference Networks to additional roles, such as research and guideline development. We'll see. Of course, as I mentioned, work is being done on joint action with respect to HTA, but again we'll see. In essence, there are many ideas and quite a few opportunities. Making them work is the goal. It will take Member States, Parliament, the Commission, and all relevant stakeholders working together to ensure that the goal is reached.

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# TACKLING UNMET HEALTHCARE NEEDS IN THE EU

*Marian holds  
healthcare  
high on list  
of priorities*



Marian Harkin,  
Member of the  
European Parliament

**Ireland's Marian Harkin first entered the European Parliament as an MEP in 2004. She is an Independent politician, but sits with the Alliance of Liberals and Democrats for Europe, the ALDE group. Born in Sligo, she previously served as a Teachta Dála for the Sligo-Leitrim constituency from 2002 to 2007 and has been a keen supporter of EAPM since its formation, as well as an advocate for personalised medicine in general.**

Marian sits on the committee on Employment and Social Affairs and is a deputy on the Economic and Monetary Affairs committee. She has worked on many occasions with EAPM, not least as an active member of the STEPs group of MEPs ('STEPs' stands for Specialised Treatment for Europe's Patients). She has also spoken at conferences and other events held by the Alliance.

In fact, in one speech at conference, she spoke passionately of her faith in personalised medicine and went on to talk about about Big Data and its role in healthcare.

On the topic of 'Realising the Vision of Personalised Healthcare through Big Data', Marion spoke about factors "that it is vital that we get right and make work if we are to make the most of the tremendous leaps in genomics since the human genome was completely and successfully mapped".

"With more and more researchers, front-line clinicians, pharmaceutical companies, patients' groups and individual citizens becoming aware of the potential of personalised medicine, the

Later in the address, Marion said that: “What the EU as a whole should be advocating is stronger cross-border sharing of Big Data, a ditching of silo mentalities, flexible regulations that take into account advances in science and technology plus proper implementation of the cross-border health directives for the benefit of every citizen.”

“Otherwise his ship will sink to the murky depths taking its ever-growing crew and ever-ageing passengers with it,” she said. “EAPM has acted as compass here to navigate these seas.”

The Alliance would like to thank Marian for her stalwart support of EAPM and her endless commitment to the best healthcare for citizens, not just in her native Ireland, but across the whole of the EU.

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**The European Alliance for Personalised Medicine has carried out a series of interviews on healthcare with MEPs, ahead of the upcoming European Parliament elections in May. Here, the Alliance’s executive director Denis Horgan (DH) discusses access to healthcare with Irish Independent MEP Marian Harkin (MH).**

**Marian is standing for a fourth term in Brussels and Strasbourg and, among other responsibilities in Parliament, is a full member and ALDE Coordinator of the Employment and Social Affairs Committee. She has a deep interest in social and public health issues and, in 2012, won the MEP of the Year award for her work in the area of employment and social affairs.**

**DH:** We all know that there are areas of unmet need when it comes to patient access across the European Union’s Member States. Is enough being done to address this?

**MH:** Ha ha! Thanks for starting with a tough one... Seriously, the EU has committed to action in order to try and remedy this, not least through its social pillar. And through an expert panel it is currently assessing quantitative and qualitative benchmarks and looking at various ways that EU funds - or what it calls ‘other mechanisms’ - may be helpful.

**DH:** So, we need to define the unmet needs, then?

**MH:** That’s right, Denis. It’s the first step. But it’s already a difficult one because, while you can define a medical need by a patient being less healthy than he or she should be, and assuming there is a treatment available, clinical reasons may exist for denying treatment, such as a lack of cost effectiveness in the face of limited resources.

The EU has asked individuals whether they have experienced a need for healthcare and were unable to obtain it, and the results according to the expert panel have produced evidence of relatively high rates of unmet need in some Member States, and even with some groups within them.

One idea is that the group getting the most access within the best-performing Member State should represent the level of access that we should be trying to attain right across the EU. The benchmark, if you will. But given the different starting levels, that’s not currently realistic. This should not stop it from being a goal, however.

**DH:** So, where do we start?

**MH:** We start perhaps by setting a benchmark of the median value achieved by the best performing Member States. The expectation is that those countries not yet at that level should narrow the gap by a given percentage, which could be as much as 50%, over a

defined period of time, for example three years.

**DH:** Wow! That sounds ambitious...

**MH:** Without a doubt it is, as it would need a significantly faster rate of reduction to unmet need than has been achieved recently in many Member States. But the general view is that this is achievable, or at least should be. For a start, the expert panel recommended that each Member State should identify groups in their own societies that are most likely to be disadvantaged. This would take into account age, gender, education, ethnicity, wealth and employment status. Each Member State should produce its own report.

**DH:** What mechanisms, if any, has the EU put in place to close the access gap and bring down the amount of unmet need?

**MH:** The relatively new European Semester system, with its Annual Growth Surveys, sets out EU priorities to boost growth and job creation for the coming year. There has been an increasing acknowledgement of the importance of access to healthcare. And one would hope so as the argument that health means wealth has been proven time-and-time again.

It is now recognised that healthcare can go a long way towards prolonging life and preventing disability and suffering. It is implicit in Treaty obligations that a high level of human health protection be ensured in all EU policies and activities. Also, nobody really now argues against health contributing to economic growth, through enhanced productivity and reduced workforce losses. In a further mechanism, the expert group on Health System Performance Assessment promotes discussions between EU Member States and international organisations on methodologies and tools to assess the performance of health systems. And its counterpart panel on Effective Ways of Investing in Health has identified that rates

of unmet need for healthcare is an increasing problem in the EU and, in 2016, set out options for how to maximise the added value of EU action on access to healthcare.

**DH:** So it seems as though the EU is dipping its toe more-and-more into the healthcare arena...

**MH:** I think we can safely say that it's more than just a toe, now Denis. More like a whole foot.

OK, health is a Member State competence, but the EU has passed plenty of legislation - much-discussed and amended in Parliament, of course - covering, for example, clinical trials, IVDs, cross-border healthcare, medical and other data and so on, and is now trying hard to get mandatory enhanced cooperation on health technology assessment through Council, albeit in the face of some resistance. Back in 2006, the Council agreed a set of common values and principles for EU health systems. One of these was access to good quality care. All EU citizens now have a legal right of access to preventive healthcare. On top of this is the right to benefit from medical treatment under the conditions established by national laws and practices.

**DH:** What should we be aiming for?

**MH:** A lot, it's fair to say. For example, all Member States, rich and relatively poor, should offer a minimum core level of provision. At the very least they should ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups; provide essential drugs; ensure equitable distribution of all health facilities, goods and services based on need, and; adopt and implement a national public health strategy that addresses the health concerns of the whole population.

These principles are incorporated in the Sustainable Development Goals, which all

Member States are committed to. On top of this, the principles enshrined in the social rights pillar, including access to healthcare, are down to everybody to employ. They fall under the competence of the EU, Member States and social partners.

**DH:** So Member States remain a vital cog?

**MH:** Absolutely. The social pillar sets out a framework for improving social standards in Europe, but at the centre of all this are Member States and their local authorities. Looking at it purely from a Member State point of view, including my own country of Ireland, there are plenty of reasons why it is in their interests to minimise unmet need - not least if politicians want people to vote for them!

The fact is that an overwhelming majority of Europe's citizens support the provision of universal healthcare within a statutory framework. Meanwhile, it is in the interests of those providing healthcare to minimise unmet need because, if they don't, the long-term costs will be huge.

The bottom line is that if systems don't identify and treat conditions at an early stage, the conditions progress and often develop complications. At that stage, we're talking about more complex and costly treatment.

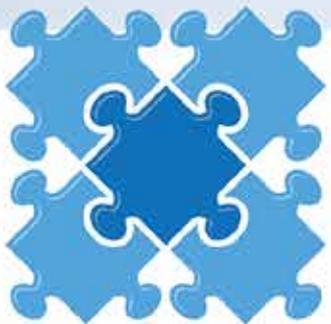
**DH:** As ever, money talks. So what about funding to improve access to healthcare?

**MH:** The expert panel that I mentioned earlier has identified opportunities for using already existing vehicles such as structural funds, research funds, and European Reference Networks. People always talk about cash, but we need to be looking at smarter ways to spend it. And reducing unmet needs in healthcare will pay off handsomely in the long run, not just financially but in social terms. All-in-all, we simply can't afford not to do it. More work needed to optimise cross-border healthcare

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members  
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A top-down view of various medical supplies including a stethoscope, surgical scissors, a syringe, and several pills and capsules scattered on a teal background.

# MORE WORK NEEDED TO OPTIMISE CROSS-BORDER HEALTHCARE



*Miriam's the genuine  
article...*

Miriam Dalli, Member of the  
European Parliament

**Former journalist and Maltese national Miriam Dalli has served as Member of the European Parliament since 2014, on behalf of the Labour Party back home, and the Group of the Progressive Alliance of Socialists and Democrats in Brussels and Strasbourg.**

**Born in St. Julian's, Miriam sits on the Committee on the Environment, Public Health and Food Safety (ENVI) - which, of course, has been much in the news lately regarding the European Commission's plans for EU-wide joint action on HTA.**

(ENVI debated and voted through a number of amendments, subsequently agreed by the entire Parliament, and now being discussed in Council.)

As part of ENVI, Miriam has previously signalled concerns in respect of ensuring Member State cooperation to avoid diseases preventable by vaccinations, as well as HTA with regards to pharmaceuticals. Malta, with its small population of some 420,000, held the rotating presidency of the EU in the first half of 2017, and had its own health agenda emanating from Valletta.

For example, given that the Maltese are statistically the fattest in the EU, the presidency put a focus on making childhood obesity a high-profile issue.

For her part, Miriam has worked often with EAPM in our pursuit of embedding personalised medicine into the EU's healthcare systems.

So it's good to know that, alongside some notable others, there's another (albeit former) journalist out there who knows what they are talking and writing about in this fast-emerging field!

EAPM would like to sincerely thank Miriam for her support for the Alliance down the years - and she certainly has something to write home about. Good luck in May, Miriam!

**EAPM's executive director Denis Horgan (DH) discusses cross-border healthcare in Europe with Maltese MEP Miriam Dalli (MD). Miriam, a lawyer by profession, has been a Member of the European Parliament since 2014 and will stand for a second term this coming May. Amongst several other roles, she is the spokesperson for the Socialists and Democrats in the Environment, Public Health and Food Safety committee (ENVI).**

**DH:** Miriam, first of all, could you briefly give a little background on the cross-border healthcare directive, please?

**MD:** European legislation, with considerable involvement from the Parliament, has established a set of patients' rights when receiving treatment in any EU Member State, other than their own.

EU citizens now have the right to access healthcare in any Member State and to be reimbursed for care abroad by their home country. This came into force in late 2013. The Directive sets out the conditions under which a patient may travel to another EU country to receive medical care and reimbursement. It covers healthcare costs, as well as the prescription and delivery of medication and medical devices.

Under the Treaty on the Functioning of the European Union, in the definition and implementation of all Union policies and activities, a high level of human health protection has to be assured. In this context, the organisation, management, financing and delivery of healthcare remains the responsibility of EU Member States. Throughout the years, case-law has acknowledged on many occasions that patients have, albeit under specific conditions, the right to access healthcare in Member States other than their own.

So, in a nutshell, the ultimate goal of the legislation is to make it easier to access

available healthcare in other European countries, as well as alternative healthcare options, or specialised treatment abroad.

**DH:** OK. Is it working?

**MD:** Well, yes and no. No, in that it's not yet working as well as it should and certainly not as well as we hoped.

It's fair to say that, unfortunately, the implementation of the Directive has not exactly gone to plan. In fact, a recent monitoring report and study from the Commission acknowledges this.

The 'Study on cross-border health services: enhancing information provision to patients', concludes that limited numbers of patients make use of their right to seek treatment in another Member States.

On a positive note, the report found that many Europeans are willing to consider treatment abroad, mainly for the chance to receive treatment not yet available in their own Member State, or to get better quality treatment.

**DH:** So why do the Commission and others think that take-up has been relatively small?

**MD:** The report has shown that there are some socio-demographic factors determining the patients' will to go abroad. In general, these tend to relate to age, employment and education.

However, it seems that there exists a general lack of awareness of the Directive - and therefore the wonderful opportunities that this Directive brings along. .

The reality is that more than five years after the Directive's transposition deadline, the number of patients who are aware of their rights and the new and enhanced possibilities to access health services abroad is still relatively low.

Having said that, patient knowledge of the Directive has improved over the past three years, but it's potential is still not being fully exploited and we're still far off from where

we want to be. It is a Directive which offers plenty of opportunities and yet few people are aware and actually make use of such opportunities.

**DH:** So who has the job of telling people?

**MD:** As part of the scheme's introduction, all Member States were tasked with setting up dedicated National Contact Points, or NCPs. Each Member State has at least one contact point whose task is to provide patients as well as healthcare professionals with information about rights in respect of a cross-border healthcare service or product. According to the recent report, there seems to be a dearth of information on NCP websites, as well as necessary information on what to do in case of undue delay, complaint procedures and dispute settlements. Citizens may also struggle to find information on how long it takes to process reimbursement or prior authorisation requests. This is unacceptable especially since the whole idea is to boost patient access to the best treatments available, wherever they may be. The idea was turned into reality with the best of intentions from Member States, the Commission and Parliament but there's a long way to go for this legislation to reach its primary goals.

**DH:** Are there any other issues that are stopping or slowing patient take-up?

**MD:** Well, aside from a lack of optimal information, actual patient mobility is a challenge. Or I should say the lack of patient mobility is an issue. At the moment, such mobility is still relatively low. This is unfortunate because, for certain groups of patients - like those suffering from rare diseases - cross-border healthcare is actually often the most appropriate and possible care. There are also issues of maintaining a continuity of care, as well as the exchange of information between health

professionals in different countries. Also, there are often logistical and administrative barriers which can, albeit unintentionally, have a negative effect for cross-border patients.

**DH:** Is it a collaboration problem? Or, more to the point, a lack of collaboration problem?

**MD:** Well, given that the Directive is intended to be EU-wide, its effectiveness has always depended upon collaboration between Member States.

But collaboration is not always as optimal as it should be. Especially in the health arena, which is a Member State competence.. The ongoing debate and resistance from some countries on mandatory joint action on HTA is a current example.

There is an argument that the legislation should have enabled a shift away from national isolationism in health. The rules were partially intended to make the EU's internal market work for health for the first time, by strengthening the freedoms relating to movement of goods, people, and services. The availability of top-notch healthcare is arguably the most important 'service' of all.

**DH:** As you know, EAPM and its members, associates and broad range of stakeholders, are key proponents of personalised medicine. For our part we were hoping that cross-border healthcare would be a considerable boon for its development. There seems to be a long way to go, though...

**MD:** It seems clear to me that proper implementation of the Directive's measures is crucial to progress in personalised medicine. For personalised medicine to reach its full potential we need freer movement of patients and data around Europe, closer collaboration on reference networks and data banks, wider access to information, and institutionalised collaboration between providers, payers, and regulators.

On top of this, a better EU-wide understanding regarding HTA is also a precondition although, as I mentioned before, the Commission is facing resistance with its plans on health technology assessment from some countries in the Council, despite being backed by Parliament.

The whole situation is difficult given the closely guarded Member State competence in this arena. But the fact remains that we clearly need to provide patients with more and better information via the NCPs that are already in existence, and we most certainly need a higher level of coherence on EU policy.

I would like to see a situation where, patients become aware of their rights, where there is an increase in take-up of cross-border health care and where healthcare services improve for the benefit of all patients across the EU.

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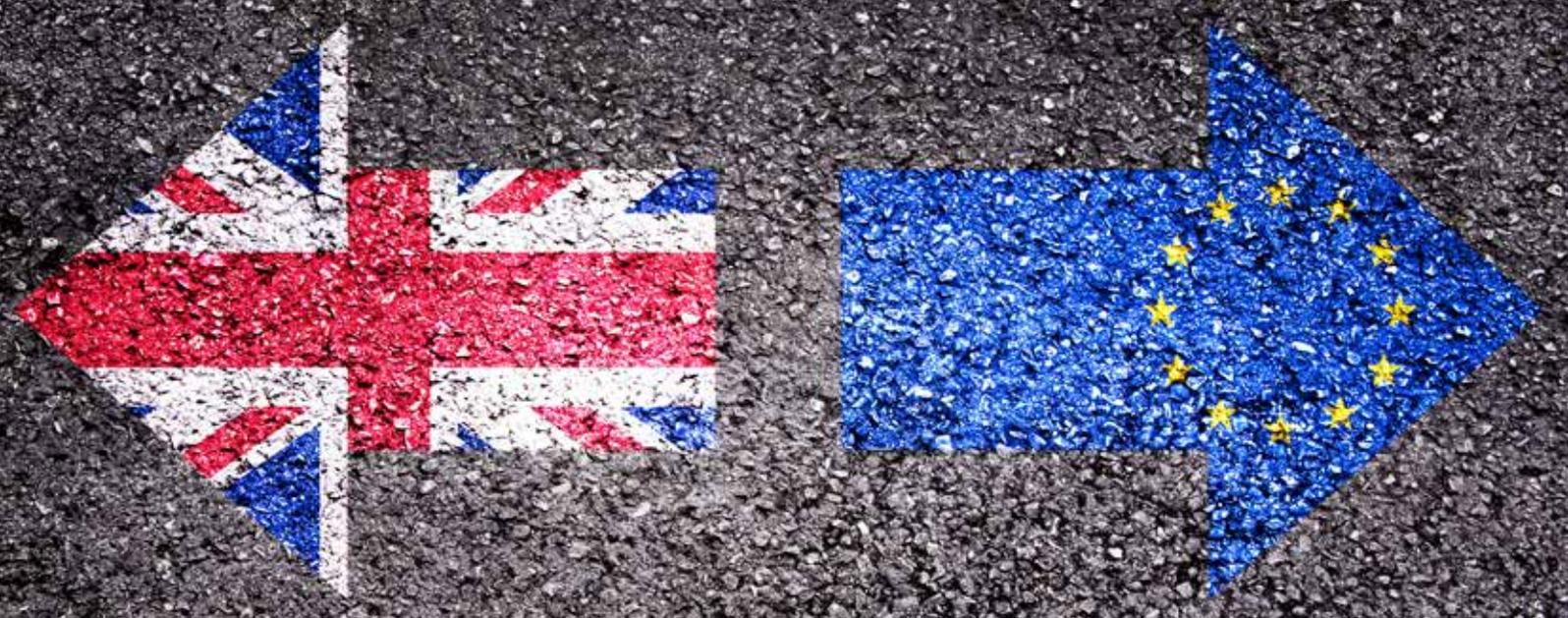
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## HEALTHCARE IN THE UK UNLIKELY TO BENEFIT FROM BREXIT



*Super Sirpa  
has the  
'personalised'  
touch*

Sirpa Pietikainen, Member of  
the European Parliament

**Finland-born Sirpa Pietikäinen has been a Member of the European Parliament since 2008, being re-elected in both 2009 and 2014. She will stand once again in May this year, and EAPM's best wishes are with her. A European People's Party deputy, and member of the National Coalition Party in her home country, Sirpa has worked hard on behalf of patients across Europe and for the cause of personalised medicine.**

As a member of the STEPs interest group of MEPs ('STEPs' stands for Specialised Treatment for Europe's Patients), Sirpa has been a great asset to the work of EAPM in past years, and we look forward to working with her again for at least the next five.

During her time in Brussels and Strasbourg, Sirpa has (among other roles) been an active member of the Committee on the Environment, Public Health and Food Safety (ENVI), and produced an opinion on the eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century. Born in Hämeenlinna, she has a Master of Science in Economics and Business Administration from Helsinki School of Economics and has previously been chairman of the World Federation of United Nations Associations.

Ahead of its late-2019 EU presidency, Finland has said it is working on legislation geared towards creating a national genome centre next year. Sirpa will be sure to have some kind of involvement going forward. EAPM has, down the years, collaborated successfully and often with the European Parliament, including with our Finnish friend, as it aims to present and push the case for embedding personalised medicine into the EU's healthcare systems. This collaboration and mutual support will continue throughout the next legislature. And, as we hit the run-up to those elections, it is well worth highlighting the role of MEPs in healthcare, while focusing on their contribution in driving forward innovation and pushing for equity and best practice in this key arena. Sirpa has been a key player in this regard.

Despite the Member State competency for healthcare, the European Parliament has overseen key areas of legislation in recent years, not least in the arenas of data protection, in vitro diagnostics, clinical trials, cross-border healthcare and, at the moment, health technology assessment.

Stakeholders have been engaged and listened to, amendments to European Commission proposals have been tabled, votes have been taken and recommendations made, not least to the Council. Core MEPs, most certainly including Sirpa, are aware that bringing innovation into healthcare systems in Europe is vital if we are to promote equal access to the best treatment options available for all our citizens, regardless of financial status and/or geographical location, while ensuring delivery of the right treatment for the right patient at the right time.

This has always been a priority for the Alliance, its members and stakeholders, and we have consistently been helped by Sirpa who has worked alongside EAPM, supports it, and strives for the same goals.

Again, we offer our thanks to her, and wish Finland good luck with its upcoming presidency.

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**In this latest interview EAPM's executive director Denis Horgan (DH) discusses the impact of the UK leaving the EU with MEP Sirpa Pietikainen (SP).**

**Sirpa Pietikainen has been a Member of the European Parliament since 2008, and she was re-elected in 2009 and 2014. Since 2014, she has been serving on the Committee on Economic and Monetary Affairs and the Committee on the Environment, Public Health and Food Safety.**

**DH:** You've spent a decade in the European Parliament and have had key roles in respect of the ENVI committee, the cross-border healthcare directive, legislation on pharmacovigilance, IVDs, data protection and more.

Theoretically, on 29 March, the UK leaves. And as it goes, so goes its influence in the institutions. Can you see this impacting healthcare in both directions?

**SP:** Of course I can. The 'leave' vote and its implementation could prove to be an

unmitigated disaster for the health of almost 65 million citizens, despite those misleading promises of lots of cash being pumped into the NHS.

And it possibly goes further than that because the 'supply lines' of research will surely suffer on a pan-European scale after Brexit starts to kick in.

Also, there has been a lot of recent talk regarding a shortage of medicines. This is nothing new but the fear is that situations will worsen. Most of the UK has already run out of warehouse storage space.

On another note, from a jobs point of view the UK has already lost the European Medicines Agency, much-needed staff for the NHS coming from abroad may struggle to be allowed to work, and cross-border healthcare is bound to suffer in both directions.

**DH:** Could you expand on that last point a little, please?

**SP:** Well, the extent of post-Brexit cooperation in cross-border healthcare remains to be seen but it's hard to see an improvement. As it stands, an estimated 1,000

UK citizens are reimbursed for treatment in accordance with the Directive each year.

France, Poland and Latvia are up there as the most popular destinations chosen by Brits for treatment while, in reverse, the UK treats around 1,500 EU patients with some 40 National Health Service hospitals involved.

Brexit could very well deliver a major blow to the long-term implementation of a Directive that is already a long-way-away from where it should be.

**DH:** Given that the UK has 73 Parliament seats, which is one less than France and 23 less than Germany, both of whom have bigger populations, plus the joint-highest number of Council votes at 29, that's a whole lot of potential influence going up in smoke, isn't it?

**SP:** Of course it is. The UK potential for influencing decisions at European level has been substantial since the UK joined in 1973, although there has been the UK's traditional wariness over a truly federal Europe - the so-called ever closer union. And Britain has never been part of the euro or the Schengen agreement.

But we've had vetoes available and a regular rebate, not to mention plenty of voices around plenty of tables when decisions have been made over more than 45 years.

When it comes to health in particular I recall that in the run-up to the referendum vote, NHS England chief executive Simon Stevens said that a leave vote would be, I quote, a "terrible moment" at a time when the NHS needs extra investment.

He told the BBC, in fact, and again I quote in full, that: "It's been true for 68 years of NHS history that when the British economy sneezes, the NHS catches a cold and this would be a terrible moment for that to happen at precisely the time the NHS is going

to need extra investment."

He also pointed out that the NHS had benefited enormously from employing doctors and nurses from the EU. And he spoke of an impact in the event that 130,000 staff could leave due to uncertainty over work visas.

Overall, I'm not optimistic for the future of UK healthcare, to put it mildly.

**DH:** So how do you think Brexit will affect the UK and its supra-national dealings with other healthcare bodies across Europe?

**SP:** Again I can't say that I'm optimistic. After all, it's clear that there's already a huge need for better collaboration across medical disciplines and borders, therefore the UK leaving will not help anyone in that regard.

As a legislative example, consider the Clinical Trials Regulation one of whose aims was and is to turn outmoded trial models into those fit-for-purpose in a health environment that has seen the rapid emergence of personalised medicine.

In this context we're looking at an EU-wide database and much greater collaboration and harmony - all for the benefit of research and, thus, eventually patients.

It's also geared towards reducing red tape and simplifying the bench-to-bedside process in many cases of innovative drugs and treatments.

Although it's probably unlikely, if the UK steps back from the legislation, it will face extra administration problems when holding trials in Member States. Even if it doesn't step back, what happens if it fails to meet EU standards down the line when any new EU-wide legislation enters into force?

The UK would be crazy not to abide by any new standards that will be agreed upon without its input, so one of the arguments for Brexit - taking back control of legislation - is nonsense if Britain wants to keep access to EU markets.

**DH:** Can you elaborate a little, please?

**SP:** Sure. As far as good manufacturing practice is concerned, the UK adheres to EU directives. These standards would allow it to export and import quality-assured medicinal products within the European Economic Area.

This would only apply, though, so long as UK standards remain equivalent to those within the EU.

Marketing authorisation is arguably more complex. Currently, one route to receiving authorisation is through the European Medicines Agency, which used to be in London, of course. This is called the centralised procedure which sees a single application submitted to the EMA.

Other routes are the decentralised procedure, which is a submission to several Member States at once, and the mutual recognition route, which sees a company apply for a product authorised in one Member State to be given the thumbs-up in others.

Put simply, once Britain has properly departed, a company would need a separate national authorisation and the centralised and/or mutual recognition routes will become difficult, especially administratively.

**DH:** What about pharmacovigilance?

**SP:** In that case, current legislation governing the procedures throughout the EU calls for speedy collection of data.

Post-Brexit, the UK may well have access to smaller data sets than those in the EU.

Not only that, but the EU may lose the opportunity to benefit from future data from the UK.

This effectively means less collaboration and sharing of information. Put bluntly, such a scenario promises to affect patients, be less efficient and more expensive.

**DH:** None of this sounds too good, but we don't know everything for certain even now...

**SP:** No, we don't. There are many unknowables at what appears to be a very late stage. The jury is still out on cross-border healthcare that I've mentioned and care for British expats living in EU countries.

As it stands, the large UK community in Spain, for example, has free access to doctors, paid for by the NHS. If the UK stays in the European Economic Area this arrangement could possibly continue.

Equally, it may turn out that expats in the UK have to pay for their own healthcare. Cross-border healthcare for those seeking treatment outside the UK may also be affected.

The bottom-line is that, in my view at least, leaving the EU is a very bad move in respect of patients and potential patients in Britain.

There is certain to be some kind of mess, but we'll just have to see how quickly and effectively we can manage to sweep it all up, depending of course on the final form that Brexit takes.

**PURE GENE-IOUS**

# Digital skills for medical students?



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*Van Nistelrooij and personalised medicine - it's in his genes*



Lamber Van Nistelrooij,  
Member of the  
European Parliament

## EUROPE NEEDS EDUCATION AND TRAINING PROGRAMMES IN PLACE NOW

**Born in Nuland in The Netherlands, Lambert van Nistelrooij has been a Member of the European Parliament since 2004. He is a member of the Christian Democratic Appeal, which is part of the European People's Party in Brussels and Strasbourg.**

**Lambert sits on the Regional Development (REGI) committee and is a deputy on the Internal Market and Consumer Protection committee.**

**In recent years, Lambert has worked often with EAPM and has been an active member of the STEPs group of MEPs ('STEPS' stands for Specialised Treatment for Europe's Patients.) This will be Lambert's final year as an MEP, and all at the Alliance wish him well for the future.**

During his association with EAPM, Lambert has attended and played key roles in many events, including our many annual conferences and plenty of roundtables.

Indeed, in a dinner speech in the European Parliament, Lambert spoke about the place and future of genetics in personalised medicine.

During his address he said: "This breakthrough form of prevention, diagnosis and treatment helps to determine the right treatment for the right patient at right time, while avoiding hazards based on familial history, environmental influences, and genetic variation.

"Genetics...have a major role to play (and) many of my fellow MEPs are very supportive of personalised medicine and its goals.

He added that the European Commission has worked hard in this field, "taking personalised medicine into account in a series of new and weighty legislative measures".

Lambert also emphasised that several rotating presidencies of the EU have played their part, too, describing it as “truly excellent to see”.

This, he said, represents co-operation at its best, for the benefit of hundreds of millions of ordinary people that make up the European Union. He added that personalised medicine is not “just an idea, it is the new reality”.

“And there is no doubt that genomics has a huge role to play in its development and growth. All stakeholders, in many different ways, are working towards putting personalised medicine firmly into the mainstream.”

Lambert also said that: “traditional medicine is the bedrock, the solid and strong foundation, on which we build the health of our citizens. And much of it has huge, huge value and is relevant today”, while insisting: “However, we must also embrace the new.”

On that topic Lambert said: “We need to get away from a one-size-fits-all model, we need to develop a new paradigm for clinical trials, we need to find ways to embed these novel technologies, such as genomics and all the other ‘omics’, into national healthcare systems. And we need to start now.

“The old and the new must meet. In the most effective way that we can manage. And we must take the best from each, and co-operate, and collaborate, and move medicine forward together. We need to start now.”

EAPM would like to thank yet another of personalised medicine’s champions for all his hard work in the European Parliament. A ‘hat tip’ to you, Lambert van Nistelrooij, MEP!

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**In this interview EAPM’s executive director Denis Horgan (DH) takes a further look at healthcare education with respect to personalised medicine. Taking part in the discussion is MEP Lambert Van Nistelrooij (LVN).**

**Lambert Van Nistelrooij is serving as Member of the European Parliament since 2004. He is a member of the Committee on Regional Development and he is also a substitute member of the committee on Internal Market. Lambert Van Nistelrooij is the European Parliament Rapporteur and Negotiation for the European Structural Funds and the European Investment Funds.**

**DH:** When it comes to education in healthcare, how important is it to engage with patients?

**LVN:** Vital, Denis. Healthcare professionals have to do this on a one-to-one basis, while policymakers and lawmakers should engage with patient advocacy groups as a key requirement to moving healthcare forward.

That’s especially true at a time when things are moving so quickly in the sphere of medicine.

There are big gaps in knowledge in relation to personalised medicine and its potential, and there is a Europe-wide need to engage, inform and empower patients and their advocates in order to embed personalised medicine initiatives at European at national levels.

As mentioned, patients certainly need more empowerment and, currently in Europe, there is a deficit in relevant materials that will increase the literacy of patients and their representatives.

Generally speaking, there needs to be more collaboration with patient advocacy groups and other relevant stakeholders so as to provide European citizens with the information they require.

**DH:** Should we develop an education strategy in healthcare?

**LVN:** Definitely. All key stakeholders need to be aware of the benefits of, and barriers to, personalised medicine delivery. Important deficiencies in knowledge and awareness of the benefits of personalised medicine among healthcare professionals and policymakers have often been identified. Across the board, there is a need for cross-stakeholder collaboration to increase literacy in three ways.

The first is to set about identifying where the gaps in knowledge and understanding of personalised medicine lie. We are well on the way to achieving that.

The second is to address these gaps by developing educational materials and tools tailored for healthcare professionals, healthcare policymakers, healthcare payers, regulatory agencies and other relevant stakeholders, which probably includes journalists, too.

Thirdly, Europe needs to produce concise educational materials tailored to particular audiences through print, online and social media, together with educational forums, workshops and round table discussions and debates. These should be delivered at both European and national levels.

Overall, when I talk about other relevant stakeholders, crucial to the successful implementation of personalised medicine is active engagement and transparent communication with patients, patient advocates, and industry.

**DH:** So, plenty to do. And probably more on top of this...

**LVN:** Indeed. For example I believe, and I know you do too, that the EU should support the development of a Europe-wide education and training of healthcare professionals' curriculum for the personalised medicine era. The EU should subsequently facilitate the development of an education and training strategy for healthcare professionals in this field.

As we know, health is all about patients and potential patients and each healthcare system within the EU features the coming-together of one set of citizens in need of diagnosis and treatment and another set entrusted to deliver.

This trust is based upon a blend of technical competence and service orientation and is steered by ethical commitment and social accountability, which forms the essence of reliable and professional healthcare. Developing such a blend requires lengthy education of healthcare professionals and, consequently, a substantial investment by policymakers and society.

**DH:** So changes are required?

**LVN:** Yes. The way in which healthcare is delivered to the patient is changing and it's changing fast. Advances in personalised medicine will and must fundamentally alter the scope, content and manner in which healthcare professionals are trained and educated.

Clearly, personalised medicine poses major challenges on education and education policies.

The European Commission came up with a Joint Action on Health Workforce and Planning with the aim of modernising skills and competences, plus a strategic framework for education and training that seeks to make lifelong learning and mobility a reality and to improve the quality and efficiency of education and training.

The EU also has a commitment to updating professional qualifications through continuous professional development that covers technical, scientific, regulatory and ethical developments.

OK, these policies were not totally inspired by the emergence of personalised medicine, but that's not the point. The principles still hold true in this case and the education of healthcare professionals in personalised medicine must be placed on the policy and political agenda as a matter of urgency.

**DH:** What are the risks if this fails to happen?

**LVN:** Well, if this doesn't happen then the inevitable result will be a scarcity of the healthcare professional capital needed to support the implementation of personalised medicine.

The subsequent lack of knowledge and skills will bring about delays in its delivery, to the undoubted detriment of patients across Europe.

For personalised medicine to deliver on its promise to transform medicine as we know it, our healthcare professionals must be ready to deliver these new methods to their patients. It is important for all to understand that personalised medicine is not just another addition to the understanding and practice of medicine, but has the potential to significantly alter medicine itself.

To get a little technical, here, cell-based diseases will be further stratified and replaced by disease entities that derive their identity from their molecular makeup, exponentially increasing their number in the process.

To prevent or diagnose these diseases, genetic testing and imaging will become more sophisticated and widespread. So-called omics technologies, which are defined as testing of multiple genes together, will certainly gain ground.

And we all know that Big Data will enable real-time diagnosis by genotyping against large databases, not just in Europe but all around the globe.

In addition, personalised treatment of diseases will often entail tailored combinations of drug prescriptions through pharmacogenomics, minimising adverse reactions and decreasing the pool of patients who are predisposed to not respond to certain treatment.

Complementing this fundamental change in the way in which disease is prevented, diagnosed and treated, is the unprecedented pace at which research and technology in the area of personalised medicine is developing.

**DH:** So some of us are playing catch-up?

**LVN:** Yes, lots of us, and we need to catch up quickly. Because none of the advances in personalised medicine will benefit patients if they are either not applied or not applied correctly.

Healthcare professionals must be aware of these fundamental and rapid changes in medicine. They must know what they must know to incorporate these benefits into daily practice.

Of course, this is different for different HCPs and may very likely cause a shift in the mix of skills and competences that are required for the proper execution of a particular job.

On top of this, healthcare professionals must be capable of navigating the ethical, legal and social issues that, for instance, surround the use of genetic testing. And they must be able to adapt the way in which they attain knowledge and skills to accommodate the rapid advancement in science.

At the end of the day, our patients will miss out on the benefit of this valuable knowledge if Europe's professionals in the field do not have the skills to identify, translate and utilise new knowledge to diagnose and treat their patients.

And as we are all aware, Denis, healthcare is all about the patients

**BETTER HEALTH  
MEANS MORE WEALTH**



## HEALTH EDUCATION FOR ALL INCLUDING THE PATIENTS

### *Lieve not short of an Opinion on HTA*

Lieve Wierinck, Member of  
the European Parliament



**Belgian Lieve Wierinck has been an MEP since May 2016. In her home country, she is a member of the Open Flemish Liberals and Democrats, which sits in the ALDE Group in Brussels and Strasbourg. She succeeded Philippe De Backer in mid-term, when he became Secretary of State in the Michel Government. Among other Parliamentary tasks, Leuven-born Lieve sits on the Committee on Industry, Research and Energy, known as ITRE.**

As ITRE's shadow rapporteur she filed a report in 2018 on the proposal for a decision of the European Parliament and of the Council on establishing the specific programme implementing Horizon Europe - the Framework Programme for Research and Innovation.

Also towards the end of 2018, Lieve produced ITRE's Opinion for the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation of the European Parliament and of the Council on health technology assessment. This contained numerous amendments.

The opinion outlined the current state of play in respect of HTA, including the fact that Member States have been working together in the area under the EUnetHTA support framework on a voluntary basis. Currently, more than 50 HTA bodies are operating in the EU, conducting assessments using different methodologies in different HTA capacities. Within the EU, HTAs are fragmented with different systems, different procedures and different requirements regarding the type of clinical evidence. This contributes to distorted market access, which constitutes an impediment to the rapid uptake of innovations in the field of

health. Current voluntary cooperation has had some successes but has not eliminated the multitude of approaches.

The opinion added that with a reinforced cooperation system for certain HTA, all EU countries can benefit from efficiency gains and make better use of their resources, thus maximising the EU-added value. The timelines and speed of bringing innovation to the market and enabling patients' access to innovation is important. The proposal aims to help the take-up of true innovation.

The standardisation of methodologies on joint HTAs should harmonise the quality and reliability, and the opinion stressed the need for an approach wherein the scientific evidence used in the joint HTAs is of the highest quality. The option noted the support for the principle of mandatory uptake of joint clinical assessments, which, it states, ensures a non-duplication of assessments and cost-effectiveness of all Member States' resources.

EAPM and many of its stakeholders are in agreement with Parliament on the need for mandatory joint action in HTA, and the Alliance congratulates Lieve and thanks her for her work, often alongside us.

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**For this interview EAPM's executive director Denis Horgan (DH) takes a look at education in healthcare, against the back-drop of fast-moving scientific developments. Here he talks to MEP Lieve Wierinck (LW).**

**Lieve Wierinck is a Belgian Member of the European Parliament since May 2016, which sits in the ALDE Group and she is a member of the Committee on Industry, Research and Energy (ITRE).**

**DH:** In the past few years we've seen huge leaps in medical technologies, not least in genetics which underscore personalised medicine. But are Europe's healthcare professionals up to speed?

**LW:** Well, let's take genomics first, since you not surprisingly mention it... Genomics in health has incredible potential through Next Generation Sequencing, or NGS, and more. The whole discipline will be a key focus as it is the foundation that enables the vast potential of personalised medicine to be realised, much of it preventative.

As you are aware, the understanding of genomics has increased substantially since

the year 2000, by which point the majority of the genome had been sequenced as part of the Human Genome Project. We are much further down the line now.

Genomics is increasingly being used in a number of areas to improve health, such as diagnosis of those with a rare disease and selection of appropriate cancer therapies, but to date this has largely been in specialist areas.

We are now at a position of needing to fully integrate genomics across healthcare systems to derive the potential benefits of personalised medicine to improve healthcare and reduce costs.

I know that one of EAPM's key goals is to improve communication between front-line HCPs and their patients, and this means that these healthcare professionals need to have up-to-the-minute knowledge of new technologies and how best to use them.

**DH:** So how do we go about this?

**LW:** Well, for a start, policymakers and lawmakers also need to get up-to-speed with the developing technologies surrounding, for example, genomic data. Meanwhile, those healthcare professionals we've mentioned

need to be able to view and understand the landscape.

When it comes to targeted and personalised medicine, healthcare professionals need to be aware that advanced profiling represents a bedrock upon which much of it is built.

Unfortunately, sometimes this awareness does not seem to be there, and other key issues are a resistance to new methods, plus a lack of risk-to-benefit analysis in respect of particular biomarkers.

Personalised medicine processes and new tools have basically sent shockwaves through healthcare systems which many argue are no longer fully fit for purpose. The foundations of the one-size-fits all structures have cracked and the walls have come tumbling down.

We need full and relevant awareness of new methodologies, and openness to the concept that personalised medicine approaches can improve healthcare while bringing down costs.

Bottom-line, there needs to be better and ongoing education, and not just among HCPs and patients, but certainly among policymakers and payers, too.

It is clear that part of what is required going forward is a long-term approach to education to ensure the translation of new therapies from laboratories to patients.

And this means that all HCPs in close contact with patients or their patients' families need to understand current aspects of personalised medicine and its latest breakthroughs in order to better understand their patients' concerns. This is crucial.

**DH:** OK, so the potential is there, and ongoing training is vital to fulfilling it. What else is needed?

**LW:** Right, there are plenty of elements, here... While it's clear that gene sequencing has huge advantages for research and prevention, there can be pitfalls for individuals and their families. In this day-and-age HCPs need to look at both sides of the coin. There is an argument that full gene

sequencing, and understanding of the consequences, should be raised in older school children as well as at universities, within HCP training courses, which should be mandatory, and with other stakeholders such as patient groups and even mainstream journalists.

For the broader policy and regulatory communities, certain aspects also need to be taken into account.

For example, there is a need to agree standards for data generation and analysis. Defining standards will ensure consistency of clinical testing and also greatly further research by facilitating greater comparability of the increasing number of sequences being performed.

Also necessary is agreeing standards around the sharing of genomic and associated clinical data, as well as promoting the uptake and alignment of existing standards and define standards for interoperability of health informatics systems.

Meanwhile, there needs to be coordinated national activity to ensure that best practice emerging with regards to clinical implementation and application is shared. And, back totally to education, we need more clinical education in genomics, informatics and personalised medicine for clinical staff. As a result of all this being put in place, we should be able to improve treatment selection, not least in cancer, and maximise success of diagnosis in rare diseases. We have all this quite staggering innovation, but we need to use it optimally. At the moment, we are simply not doing that.

**DH:** What would you suggest is the best regulatory framework, for example to support innovation in genomics?

**LW:** We can ask what needs to change? And we can ask does anything actually need to change across the labyrinthine legislative landscape to add more support to the use of genomics in personalised medicine? Well, many would argue that there are privacy

and protection issues which could underpin an argument in favour of a new evaluation approach to profiling and next-generation sequencing technology.

Meanwhile, patient safety is paramount as is consumer confidence, so regulation can play a part.

Without these two elements and arguably more, such as guaranteed quality and accuracy, innovation in this area will slow, which will inevitably have an impact on patient health, as well as increasing the likelihood of a failure to bring down costs. Also, it is often said that there is a need to increase transparency for patients, physicians and regulators in respect of what data is available.

What is certainly required is an open debate to determine the best approach to both regulation and also education in this area, and others, with innovation being allowed to flourish, albeit under strict guidelines.

As a promoter of personalised medicine, Denis, you will know that, overall, taking the approach of putting patient outcomes first when considering regulatory issues is the only way to make this transition in an effective manner.

**DH:** How important is patient/HCP communication and do patients also need to be educated?

**LW:** There needs to be an emphasis placed on communication in consultations. Decision-making in this new era of healthcare is a key aspect when implementing personalised medicine.

Patients should have an equal role in any decisions made about their treatment, and this requires them to be able to input vital information to the conversation, such as their lifestyle and work circumstances, so they need to be properly informed.

The fact is that it has to be fully recognised that the patient is at the centre of his or her own treatment and health-related decisions, and relevant skills on the part of HCP need to

be developed accordingly.

We need to improve health literacy for all and, crucially, improve the communication between the core actors of health-decision making which, as I've said, must include the patients. Always.

# INTERVIEWS

## SECTION 2

HIGH LEVEL STAKEHOLDER INTERVIEWS



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# BIG DATA

## AND ENHANCING TREATMENT OPTIONS



Louis Denis,  
US TOO Belgium

**In this interview EAPM's executive director Denis Horgan (DH) talks to patient advocate Louis Denis (LD) about the possibilities brought about by Big Data.**

**Louis Denis career as an urological oncologist started as a founding member of the Genito-Urinary Cancer group of the European Organisation for Research and Treatment of Cancer (EORTC). He served the EORTC in a number of functions including President from 1988 till 1991.**

**His recent interest is focused on the organisation and support of cancer patients associations in general and prostate cancer associations in particular. He serves as director of US TOO Belgium and advisor of the Oncologic Centre Antwerp as honorary director. He is an ex-officio board member of Europa Uomo, the European Prostate Cancer Coalition.**



**DH:** How can Big Data help us in a medical sense?

**LD:** Let's start by saying that this phenomenal amount of data could, and should, be used to put hundreds of millions of patients at the heart of the personalised medicine revolution.

Big Data has been described as, I'll check my notes, "extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations.

"In general Big Data sets require advanced or specialised methods to provide an answer within reliable constraints".

Medical research, clinical trials and more are by themselves generating unprecedented amounts of the Big Data that is moving treatments forward in many disease areas.

Obviously, patients, researchers and industry all need information. And there's no doubt that there are ever-more new ways of collecting it. But to put patients right in the centre of the Big Data phenomenon, individuals, and especially those who share all that very private data about their health, should be in control of their own information, become empowered through it, and use it to help themselves and others when it comes to health.

Initiatives such as MEGA - the Million European Genomes Alliance - offer the possibility of sharing huge amounts of genomic and other medical data for the benefit of all. Also, the sharing of clinical-trial data across borders is vital due to many more rare diseases now being identified with, by definition, smaller patient groups. Patient data on rarer diseases must be collected, shared and analysed. This would allow more information-flow with the result that diseases are identified earlier and new drugs can also be developed. This is not only the case with rare diseases, but the arena is certainly smaller and more focused. And it's not just me saying all this. Management groups from HMA and EMA have concluded that "much may be gained from the rational use of Big Data in a regulatory context for approval and monitoring of efficacy/effectiveness and safety of medicines, medical devices and combinations thereof. Indeed many future activities necessary for regulatory progress will not be possible without the use of Big Data technologies".

**DH:** It's not so simple to make the most of the potential, though, is it?

**LD:** Sadly not, Denis. There are clearly huge moral and ethical questions about the collection, storage, sharing and use of medical and other data. It must be done within robust frameworks that protect the patient but, at the same time, don't torpedo those scientists

looking to find new disease cures and better drugs and treatments.

Let's never forget that most patients are happy to share their personal medical data given the right circumstances.

However, there needs to be the right regulatory environment, and regulators as well as healthcare professionals need to be trained up. We need to highlight regulatory needs for data generation, plus standards, develop unified strategies and, crucially, support patient communication channels to increase awareness of the value of data sharing. Those of us that know and understand it recognise its value.

**DH:** Europe's scientists and researchers are clearly extraordinary, but they all need access to up-to-the-minute data. How do we improve what is currently a sub-optimal situation?

**LD:** Well, we all know that making better use of Big Data in a medical sense will achieve several things, including reducing current inequalities in access to innovative technologies such as genetics.

It would also lead to the development of deeper and broader collaborations across European researchers and provide a database of enormous lasting value to all in the EU. But we need to substantially improve cooperation and collaboration among all stakeholders as well as encourage all players to communicate better across inter-connecting areas in healthcare, and even within their own fields. Patients have a key role here, and must be added to the mix, right at the centre.

The technology is out there, but there is a need for much better collaboration, as I've said, and more investment in research and innovation.

The European Union, Member State policy makers and regulators are critical in helping shape the landscape for the successful

implementation of genomics and related technologies in healthcare. As, of course, are the patients.

**DH:** Let's talk briefly about cancer...

**LD:** OK. First of all, using data to understand the cause of disease, the medical profession can then develop new and better drugs and therapies, as well as developing other health interventions targeting the individual.

There is more-and-more evidence emerging that the proper use of Big Data in many medical contexts can save lives. And it can certainly help to bring about more and better cancer research.

Most of us agree that cancer research needs more flexibility and less obstacles. Research into rare cancers, for example, is often international. So, to ensure the ability to transfer data between countries, we need to simplify the exchange processes.

The bottom-line is that we need to make international data transfers easier in order to benefit patients now and in the future.

Specifically in cancer care, but in healthcare generally, there's a large disparity in survival rates across the EU's Member States. But the sharing and optimal usage of Big Data for research could certainly help to change this.

**DH:** Do we have the money to make this all happen?

**LD:** Well, prevention can substantially cut costs, while adding to the wealth of nations as people can work and generate wealth for longer, while using up less resources such as hospital beds and the valuable and limited time of healthcare professionals.

Not only that but, as discussed, while Big Data offers the potential to revolutionise the effectiveness of health interventions,

it can also help ensure the more effective management of resources in what are increasingly cash-strapped public healthcare systems.

So, at least in this context, it's not always and only about pumping more money in, but making better use of what we already have at our fingertips.

We are all aware that, over the coming decades, the financial sustainability of health systems will become more and more challenging as the population ages. The number of over 65s in Europe will increase by 75% by 2060.

Alongside this, there's likely to be an associated rise in chronic illness which will lead to spending on health and social care reaching unsustainable levels unless we can increase the quality of health outcomes as well as the efficiency of healthcare resources.

**DH:** So Big Data can help in this context?

**LD:** Well, it's widely acknowledged that value-based approaches to the management of care are an ideal way forward. Big Data will be a key enabler of this. And in future, physicians and health managers should have real-time, real-world evidence on what works and what doesn't for each patient. And other trends, such as mHealth, will bring the benefits of Big Data much closer to the patient. And the patient is the biggest stakeholder of all when it comes to healthcare.

The bottom-line is that science will not stop moving forward, and the use of genetics in personalised medicine, the existence of biobanks and the availability of super computers for data-processing purposes, will all combine to make the potential for the use of Big Data absolutely massive in the arena of health.

As patients, we're all for it!

**EMPOWERING  
EUROPE'S PATIENTS,  
TODAY AND TOMORROW**

I'M **SHARING** ALL  
MY VITAL PATIENT INFO  
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European Alliance for  
Personalised Medicine



# HEALTHCARE AND THE DIGITAL SINGLE MARKET



Stephen McMahon,  
Irish Patients' Association

**For this interview EAPM's executive director Denis Horgan (DH) looks at the European Commission's Digital Single Market strategy, with an onus on health. Here he talks to patient advocate Stephen McMahon (SM).**

**Stephen McMahon is Chairman and co-founder of the Irish Patients' Association (IPA) and is a voice for patients in Ireland. The Irish Patients' Association listens and learns from the many experiences of patients, their families and carers and helps resolve their issues and bring problems to the fore.**

**The ultimate goal of the Association is a world class, patient centred healthcare system that is built on Patients Rights, Responsibilities and trust.**

DH: OK, so what exactly is the Digital Single Market?

SM: Well, this strategy was put into place at the start of the current Commission's mandate on the basis that, while the internet and digital technologies are transforming our

world, barriers online mean citizens miss out on goods and services, internet companies and start-ups have their horizons limited, and businesses and governments cannot fully benefit from digital tools.

This needs fixing.

The idea was, and is, to bring the EU's single market into the digital age. At the time, the Berlaymont reckoned the strategy could contribute €415 billion per year to the EU's economy and create hundreds of thousands of new jobs.

DH: And how is it doing?

SM: In May 2017, slap-bang in the middle of the strategy's mandate, the Commission published a mid-term review, which took a look at progress made, and outlined further actions on online platforms, data economy and more.

The review identified three main areas where further EU action is needed, and there were and remain to develop the European Data Economy to its full potential, protect Europe's assets by tackling cybersecurity challenges, and promote online platforms as responsible players of a fair internet ecosystem.

At the time of the survey, and there's no reason to think this has changed, two-thirds

of Europeans - or 66% - thought that the use of up-to-the-minute digital technologies has a positive impact on society, the economy and their own lives.

One can assume that the 66% will include plenty of current patients, while the rest are potential patients, of course.

**DH:** Let's look at the background and implications for healthcare...

**SM:** There are lots of areas in which digital upscaling will have an impact on healthcare. For example, eHealth apps, electronic medical records, cross-border health care, and so on. What is very important for patients is the ability among healthcare professionals to harness various health data in real time to help them make faster and better medical decisions.

Meanwhile, real-world evidence is crucial to the implementation of adaptive clinical trials. And the opinions of patients with conditions for which there are currently limited treatment options must be incorporated when considering alternative evidence bases such as real-world data.

Meanwhile, the EU should allow for a wide scope of eHealth and mHealth applications without over-regulating the sector, employing what the US Food and Drugs Agency has called a 'light touch'.

As the discussion has continued, a number of stakeholders including patient groups have already set out issues in respect of the Digital Single Market.

They highlighted barriers to the implementation of real-world evidence, which included the fact that the required data infrastructures do not exist everywhere in Europe, data collection systems are not harmonised and many of the most successful implementations are customised locally, and the technology is evolving more quickly than regulation can adapt.

Other points were that regulatory authorities at the Member State level are not currently

equipped to base decisions on real-world evidence, the 'Right to Be Forgotten' data protection legislation is felt by many to compromise the ability to use real-world evidence in clinical development, and next-generation healthcare harnessing real-world evidence will be increasingly multi-sectoral and multidisciplinary, which will challenge the current status-quo of regulatory oversight.

Of course, we now also have the General Data Protection Regulation, known as GDPR, under which 'Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health'. That's on top of the GDPR requirements.

So that's a lot of barriers and potential ones, Denis.

**DH:** What has the Commission said about digitation in healthcare?

**SM:** Well, of course it has acknowledged that digital technologies can help improve people's health and address systemic challenges for healthcare systems.

The Commission is, and has been, working with Member States to ensure that citizens can transfer their basic medical information electronically when receiving treatment in another Member

State, and use e-prescriptions to get their medication dispensed.

This is nowhere near functioning optimally yet, but the EU is optimistic that it should be operational by 2020 in most Member States. In the meantime, the two recent Regulations on medical devices were adopted in 2017 and take into account a comprehensive EU-wide database on medical devices called Eudamed. This database serves the development of innovative digital diagnostic and therapeutic solutions, as well as the early detection of safety issues.

So far so good.

**DH:** Is anything else happening in the EU's digital arena that can benefit patients?

**SM:** Quite a lot, actually. DG SANTE, for example, is fully involved in setting the key priorities in information and communication technology standardisation, and health is one of the 10 sectors selected for closer review. As for the relatively new European Semester scheme, there has been a call for improvement of integration of care through up-to-date information channels such as e-health. In the EU's country-specific reports, moves towards eHealth systems have been very strongly advocated as a means of delivering cost-effectiveness and growth. The country profiles included in the Semesters have a specific section on eHealth and allow mapping of telemedicine needs at national level.

On top of this, new technologies, medical appliances and diagnostic techniques require technical know-how in addition to clinical knowledge and new ways of working. The eHealth Stakeholder Group previously recommended that eHealth is part of the curricula of healthcare professionals. We couldn't agree more.

**DH:** Anything with respect to patient empowerment?

**SM:** Well, as you would suspect, this is always my big issue and that of any patient group. The Commission rightly says that health e-literacy empowers citizens and patients to better manage their health. At least in theory. And we need more of it.

Cooperation is key, too. Healthcare is a priority for all citizens - just ask them - especially in an ageing society. Our healthcare professionals are drivers in delivering healthcare, yet Europe needs to recognise that there are possibilities for collaboration between healthcare systems across the EU and, furthermore, grasp them. Digital technologies should aid and speed this process.

Meanwhile, the digital single market strategy certainly opens up possibilities for specific initiatives on telemedicine and mHealth. We all know that telemedicine has a large potential to improve the future of health services, being theoretically able to improve the quality of diagnosis, care and monitoring. It should also increase patient empowerment as well as the co-operation between doctors and between doctors and patients. Another benefit could and should be an improvement in access to healthcare, one of the three pillars for the EU agenda on health systems, and the real 'biggie' for all patients and their representative groups.

**DH:** Are there any specific issues and problems surrounding, for example, telemedicine?

**SM:** Yes. Despite the fact that we're definitely going in the right direction, the Commission itself knows that the uptake of telemedicine services is often slowed by concerns about the security of data, as well as the quality in certain circumstances.

Greater standardisation could increase trust and confidence in the use of telemedicine applications, particularly amongst healthcare providers and individual healthcare professionals.

Lack of interoperability of health information systems is another huge issue that needs to be tackled. And quickly. In all areas, actually. What's the point of all this brilliant new technology if countries, regions, hospitals and even departments within the same hospital can't 'talk' to each other?

The problems usually arise due to differing technical standards, and a big bug-bear here is that, often, patient data cannot be transferred across national borders. This is hardly helpful in the context of electronic health records and cross-border healthcare, is it?

But, as I said, Europe is going in the right direction, we're just not fully up-to-speed yet.

# **PUTTING THE PERSON INTO PERSONALISED MEDICINE**

I NEED TO COLLOQUIATE  
AND ENABLIEMESQUE  
MY CLINIQUENTIATES!!

YOU MEAN  
ENGAGE &  
EMPOWER  
YOUR  
PATIENTS?

THAT  
TOO!



COMMUNICATION...



European Alliance for  
Personalised Medicine



Ken Mastris, European  
Cancer Patient Coalition

## WE NEED TO KNOW MORE ABOUT OUR HEALTH. LITERALLY...

**In this modern era of personalised medicine, patients are demanding to become more-and-more involved in their own treatments. But it has become clear that neither patients nor healthcare professionals as yet know quite enough. The same holds true for regulators and policymakers.**

**Here, as part of a series of interviews for EAPM, the Alliance's executive director Denis Horgan speaks to patient advocate Ken Matris from European Cancer Patient Coalition about health literacy.**

DH: Let's start with a fairly basic yet possibly contentious question... Who knows best, the physician or the patient?

KM: Ouch, Denis! OK, well the first reaction for many would be 'the physician', of course, but the times are changing quickly and, nowadays, it depends on many factors. Clearly our HCPs are trained to be experts in diagnosing conditions and suggesting treatments.

On the other hand, the patient obviously knows more about his or her own lifestyle, work environment and how much he or she can rely on family-care resources, for example, so co-decision is a growing part of modern-day medicine.

DH: Presumably, such co-decision can only work if both 'sides' have a good degree of health literacy.

**KM:** All healthcare professionals in close contact with patients need a solid knowledge of current aspects of medicine and its latest breakthroughs.

On the other hand, patients need to be as literate as possible and, let's be very clear here, it is not just patients, but potential patients. The more we know, the more opportunities we have to take... let's call it evasive action in a preventative sense.

By that I mean changing lifestyles by lowering the risk of lung cancer by giving up smoking, and lowering the risks of contracting diabetes by making changes to how we eat, how we exercise, how much alcohol we drink and so on.

Staying healthy longer not only benefits the patient on a personal level, but it makes sense for society in general, not least financially. Health means wealth, as we all keep saying!

**DH:** So, are doctors keeping up to speed?

**KM:** To be honest, as an unwanted backdrop, there's an unfortunate yet undeniable reluctance among some doctors and nurses to embrace new technologies and move on to modern, more targeted medicines and treatments.

All this fast-moving science undoubtedly makes life more complicated. And no matter how good the HCP is, it's difficult to keep up-to-speed with all developments. Nobody is born understanding difficult topics such as a patient's genetic profile, for example.

On the other hand, patients are growing more-and-more knowledgeable about their conditions - albeit often through the internet, which of course, can pose its own problems in respect of misinformation or the misinterpretation of information.

Therefore what is key, or should be, is communication between the two, based on knowledge, or in other words literacy.

**DH:** It sounds simple...

**KM:** Ah, but health literacy has various aspects. Within the medical profession itself there is often a lack of understanding between different silos, which is to be expected in part given the different areas of expertise. This also extends to different stakeholder groups, even before we consider the patient.

While all this is or isn't going on, the patient may struggle under the weight of extra knowledge, although avoiding old-style patronising of him or her is key to a solid, modern relationship.

But evidence has shown that strengthening health literacy builds individual and community resilience, helps to address health inequities and improves health and well-being.

Many campaigns in the past, present and doubtless the future attempt to focus on patient education, which is great as far as it goes, but the support networks for patients trying to follow one path or another are not always the best.

**DH:** How much of an issue is lack of health literacy in EU citizens?

**KM:** I'll put some figures out there... A European Health Literacy Survey found that nearly 50% of adults tested in eight EU countries have inadequate or problematic skills "that adversely affect their health literacy".

As I touched on before, this tends to lead to the individual making less healthy choices, indulging in riskier behaviour, and, in patients already diagnosed with a disease, it brings about poor self-management of chronic diseases and lower adherence to medicine regimes.

The end result, inevitably, is more time spent in hospitals and doctors' waiting rooms, leading to further draining of resources in what we can see are already-stretched healthcare systems.

**DH:** Any other benefits of health literacy?

**KM:** Yes. As a WHO report has pointed out, health literacy is an important form of social capital, an asset for individuals and communities. High literacy rates benefit societies, with the more-literate individuals participating actively in economic prosperity. For the benefit of all, it clearly needs to be better promoted.

And let us not forget that politicians, the media, civil society and employers can all play a part in addressing the challenges of health literacy.

For example, key personnel at the European Commission should undergo 'awareness training' in fields that are moving swiftly, such as personalised medicines.

This would allow them an insider view, which should help to ensure that any ensuing policies or recommendations to Member States would reflect current and future needs. It would also make it more likely that grass-roots health literacy is stimulated at national level and pan-national level.

**DH:** When you say 'better promoted'...

**KM:** Health promotion has been described as the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and to realise aspirations, to satisfy needs, and to change or cope with the environment.

These are worthy goals, of course, but difficult to achieve across all countries and socio-economic groups.

However, Europe must strive to do this, as around 350 million working days are lost in the EU every year, which is bound to rise as

the number of workers over-65 continues to grow rapidly.

At this point I'll say that there is therefore obviously a very strong case for businesses to invest in health literacy.

**DH:** So how do we improve our health literacy?

**KM:** Not easily. Health information is often inaccessible because, says the WHO, the literacy demands of health systems and the literacy skills of average adults are mismatched.

Then there's eHealth literacy. This means the ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.

The problem is that it combines six types of literacy, which are traditional, health, information, scientific, media and computer. I think you'll agree, Denis, that that's a lot of 'literacy' for anyone to handle.

In the end, at the core of the ideal, modern relationship between healthcare providers and their patients is increased communication to facilitate co-decision making. And I mean that literally...

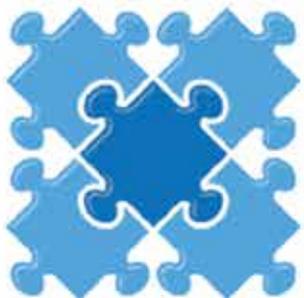
The European Alliance for Personalised Medicine upholds what it calls a "P4" medicine strategy. The 4Ps are predictive, preventative, personalised, and participatory. EAPM believes that these elements will help embed personalised medicine into European health systems.

It also says that public health and prevention are two key pillars of personalised medicine, and emphasise the increasing importance of participatory patient involvement and empowerment.

**EMBED INNOVATIVE  
PERSONALISED MEDICINE  
INTO THE EU'S  
HEALTHCARE SYSTEMS**

# PERSONALISED MEDICINE ?

CAN'T YOU JUST  
TAKE ONE OF  
MINE?



European Alliance for  
Personalised Medicine

# IS PERSONALISED MEDICINE THE ROUTE TO A HEALTHY WORLD?



Gordon McVie, European  
Alliance for Personalised  
Medicine

**Here, as part of a series of interviews for EAPM, the Alliance's executive director Denis Horgan speaks to the organisation's co-chair Gordon McVie about various aspects of personalised medicine.**

**DH:** Gordon, although a cancer expert you've seen the development of personalised medicine from all angles. Let's start with the question of how important is genomics?

**GM:** Extremely important. Use of the advanced genomic instruments now at our disposal is needed to achieve a healthy society, but access to information from the huge amounts of clinical, lifestyle, and environmental data now also available is crucial.

We all tried to find a balance within the much-argued over General Data Protection Regulation between data sharing in health, for the benefit of citizens, and privacy, which is also for the benefit of citizens.

The simple fact remains that most patients are willing to share their data for the benefit of today's patients and those that will follow.

Now the challenge is how best to gather, store, share and interpret Big Data, ethically, safely and within robust privacy boundaries.

Going forward, it is crucial that personalised medicine and public health leaders, alongside IT experts, researchers and more, work together to ensure that responsible data sharing allows patients and citizens to receive the maximum benefits for their health.

**DH:** Can you see personalised medicine replacing what we might call 'traditional' healthcare?

**GM:** No, not at all. Instead, personalised medicine offers a more-nuanced added value that uses increased knowledge of the individual to inform both health-preserving and quality-of-life-preserving decisions.

Where older and established treatments work well, they should be retained. If it ain't broke, don't fix it.

However, sticking to a one-size-fits-all approach for diseases such as cancer is no longer justifiable from a healthcare or quality-of-life perspective. It also represents a waste

of precious health resources, which we can ill afford. In the not-too-distant future, as well as there being better prevention, the emphasis will undoubtedly shift away from treating illness and move toward maintaining an individual's health.

**DH:** So how far down the line are we when it comes to personalised medicine?

**GM:** Well you could argue that a lot of the achievements remain theoretical, because so much more needs to be done.

Take cross-border healthcare. This is a superb concept which many stakeholders and not least the European Parliament worked hard to make a reality, yet we can hardly pretend that it has been implemented to an optimum level so far.

The idea was to clarify and reinforce citizens' rights to choose where to seek medical treatment, and in what circumstances. But while things are gradually improving, Member States were slow to implement it.

One could argue that this is one result of Member State competence in healthcare, but such national isolationism is what it is, despite recent over-arching legislation from the EU in areas such as clinical trials, IVDs and now health technology assessment.

The battle lines have already been drawn on HTA, of course, and we await developments with interest.

On the whole, EU policy in healthcare is geared to persuading if not forcing countries to cooperate, as well as healthcare providers, purchasers, and regulators. We are talking about the development of European reference networks, especially for rare diseases, and interoperable e-health solutions, for example.

Remember that a high level of human health

protection is to be ensured in the definition and implementation of all EU policies and activities, which should provide new support for medical advances in research, cohesion, competition, industry, and intellectual property.

Hopefully this will happen, but it hasn't yet, at least not as well as it could.

**DH:** How important is communication and cooperation between Member States?

**GM:** It can't be underestimated.

Aside from cross-border healthcare, we need to work harder on making electronic health records more common and interoperable, make the most of the brilliant research going on in the EU by collaborating and not duplicating - mandatory joint-action on HTA should help immensely, if we ever get it - and there needs to be a breakdown of silo thinking, not just among various disciplines but also Member States and even their regions.

It may be said that 'talk is cheap', but it's also a necessary element in enhancing cooperation, efficiency and value.

**DH:** So there are undoubted challenges, but would you still say that personalised medicine is the way to go?

**GM:** Absolutely, Denis. The genie is out of the bottle, now. You only have to look at the great progress we have made in cancer diagnosis and treatments on the back of the leaps in genetic science.

In a fast-moving field that sees treatments and medicines tailored to a patient's genes, as well as his or her environment and lifestyle, we are aiming to give the right treatment to the right patient at the right time. It also works in a preventative sense which extends lives, enhances lifestyles and saves hard cash

and resources.

The technology is marching on and seems unstoppable.

And when it comes to that serial killer cancer, a field in which personalised medicine has already had major effects, treatments that target cancerous mutations have become a reality.

But against the backdrop all of these new developments, the importance of access to medicines and innovative treatments across the EU is coming under the microscope.

Access is multi-faceted and involves availability, affordability and the insurance of quality.

Among the basic tenets of the EU are equality and access to the best healthcare for all, regardless of who or where they are. This is clearly not the case at the moment.

Unfortunately, despite the existence of innovative new drugs, new technologies and developments in medical science, many citizens are not able to access them, often due to high costs.

Other issues include overly bureaucratic reimbursement procedures, so we definitely need a regulatory environment which allows early patient access.

It's a long road, with many existing and potential bumps along the way, but at least the journey has begun. And there will be no turning back.

With a new European parliament and a new European Commission set to take office next year, Europe has an opportunity to generate more coherent management of care and wider access for patients.

Personalised medicine is here to stay. But I will say this, if the opportunities are missed -

or mishandled - the damage will be felt not only by today's patients, but by tomorrow's patients too. We can't let that happen.

**BEST TREATMENTS  
IS IN OUR DNA**

# Belgium Speaks out





# THE UNHEALTHY CONSEQUENCES OF DISCRIMINATION



Francesco De Lorenzo,  
Cancer Patient Coalition

Here, EAPM's executive director Denis Horgan (DH) discusses the financial and genetic discrimination that past and present patients have faced, and what could be in store for those in the future, with Francesco De Lorenzo (FDL), representing the European Cancer Patient Coalition.

Francesco de Lorenzo is a colon cancer survivor, President of the European Cancer Patient Coalition (ECPC), President of the Italian Federation of Cancer Patients Organisations (FAVO), President of the Italian Association of Cancer Patients (AIMaC), and co-founder of Italy's first Cancer Information Service (CIS).

**DH:** We've all heard about the dangers of genetic discrimination, and we'll come to that later, but can you first talk us through financial discrimination, please?

**FDL:** Well, it's all about access for patients to the best healthcare possible, or lack thereof. It differs hugely from some Member States to others and often also within regions.

You could describe financial discrimination as the inability to afford private healthcare insurance, or you could point to lack of the best treatment if the country that one lives in doesn't have the resources to pay for it.

And this has a knock-on effect when it comes to cross-border healthcare, of course. The directive, even if lacking in its implementation,

is an extremely valuable tool. However, if I would have to rely on another country that provides a treatment I need, but it is more expensive than the reimbursement I may get in my own country, this would make it impossible for many cancer patients in Europe to make the most of the cross-border healthcare, or at the very least make it extremely difficult. The Cross-Border Healthcare Directive needs to be much better implemented, and I am confident that recently adopted European Parliament report on its implementation will provide guidance to the European Commission to secure benefits to patients, especially those with rare diseases and rare cancers.

And that's not even taking into account time of work and travel costs.

Also, in the case of you or I having a rare disease, how do we get to a clinical trial, assuming we even know about it, and how can we or even our country afford the high prices charged for orphan drugs?

These are all examples of what is effectively financial discrimination and there's lack of support in the existing legislative frameworks for addressing it. We as patients are very proud of the recommendations of Access to Medicines report of the European Parliament as well as the very recent EP report on Cross-Border Healthcare Directive implementation. We ask European Commission to further guarantee access to information, medicine and medical treatment for patients with rare diseases throughout the EU, and to strive for improved access to early and accurate diagnosis.

**DH:** Any other issues?

**FDL:** The bottom-line is that unhealthy divisions, fiscal or otherwise, don't facilitate access to the best available treatments for individual patients. In Europe, there are plenty of health inequalities. In 2015, the European Cancer Patient Coalition has published a

White Paper titled "Challenging the Europe of Disparities in Cancer" showcasing these health inequalities and significant disparities between European nations for patient access to medicines, surgery and radiotherapy. Moreover, regional intra-country variations are also evident, leading to differences in survival within individual countries. Four years on, since the publication were still fighting to address the disparities mentioned in the White Paper. To stress further this point, we're proud to have contributed to the CanCon recommendations on health inequalities. And also here in Europe the problems of creating sustainable and equitable healthcare are never far away. Cancer knows no geographical boundaries. Neither do cancer disparities, which are universal across Europe, from Aarhus to Athens, from Bonn to Bratislava.

In this new and exciting era of personalised medicine, about which you know plenty, the key pairing of sustainability and equitable access affects all of the European Union's hundreds of millions of potential patients.

Last November, ECPC in partnership with EAPM, launched the first ever Personalised Medicine Awareness Month with a theme 'Cracking the Cancer Code'. And as you very well know, the aim here is to significantly increase awareness within the patient and HCP community around diagnostics and their critical role in selecting the right cancer treatment and empowering personalised medicine. The major problem for patient access to personalised medicines remains that healthcare systems are not ready for it. To achieve change we need to drive the creation of creating enabling legal frameworks for access to personalised medicine, which has such a tremendous potential for sustainability of our healthcare systems and more importantly the potential to save lives and improve quality of life of cancer patients.

It is clear that individual and community health is influenced by several factors, some

of which I've mentioned. These include work, wealth - or lack thereof) - background, lifestyle, country of origin and more. All of the above are central to the patient and the patient is central to his or her own treatment. Not so long ago 'The Marmot Review' showed that other factors are always important in explaining life expectancy differences between areas - and, by extension, one would conclude countries. These include employment versus unemployment, deprivation among older people and, perhaps surprisingly these days, gender.

Perhaps key among all of the reasons for a lower life expectancy is the issue of access to new drugs and treatments. What if we can identify the right treatment for the right patient the first time around? We can avoid wasted resources, that may potentially free up healthcare system resources and increase availability and access to high quality healthcare provision.

Of course, there are many issues around pricing, reimbursement and incentives, while frameworks need to be put in place that can support research as well as the general needs of the research communities.

**DH:** What about carers in this context?

**FDL:** I'm glad you brought that up, Denis. The European Parliament has already taken a look at the volunteer sector in Europe, as well as methods to address the low participation of women in the labour market.

The European Commission in 2015, meanwhile, launched an initiative entitled 'New start to address the challenges of work-life balance faced by working families'. In a communication, the EU executive stated, and I quote, that "the current system entrenches the role of women as primary care-givers for children and elderly or frail relatives - a problem which is likely to get worse due to the effects of an ageing

population and reduced public expenditure related to services - especially health, long-term care and childcare services".

At ECPC, we took this issue to heart for the unsung heroes that cancer carers are when we looked at the existing support measures across Europe looking for concrete actionable solutions that can be taken up at EU level but also in individual countries.

The European Commission flags up a lack of appropriate leave arrangements, and adds that while some employers develop family-friendly policies "in general, attitudes to the organisation of work tend to remain fixed around on-the-job presence for full-time hours or more".

The White Paper on Cancer Carers brought up many examples showing how aggressive and long-lasting forms of cancer impart a particular burden on carers requiring a robust framework to support their role.

Statistics show that women carers especially tend to work less hours in paid employment while spending more time in fulfilling the unpaid care responsibilities.

A higher proportion of women also work part-time where the pay gap is more than 37%, especially when they care for children or other dependents.

How's that for financial discrimination?

Financial toxicity and gender issues are only a few examples of numerous challenges 100 million carers are facing in Europe today.

Certainly, front-line carers are key to filling the ever-widening gap between healthcare needs and dwindling resources, and this needs to be recognised fully.

Together with ECPC, we have been advocating for carers' recognition in the Work-Life Balance Directive for Parents and Carers which has recently concluded inter-institutional negotiations. The most important positive outcome of this, that we will finally have a formal definition of carer. It is a small but such a valuable step in providing the much-needed support for cancer carers to access social security benefits. I'm confident

it will be an example to build upon at national level to create effective policy frameworks for supporting carers.

**DH:** How about the dangers of genetic discrimination?

**FDL:** Well, we all know that genomics is big, big news these days. Not least in relation to Big Data. The two go hand-in-glove to a large extent.

But certainly with the expansion of genetic knowledge and fast, modern Next Generation Sequencing techniques, moral and ethical aspects are often uppermost in many citizens' minds. That also holds true for policymakers. Clearly, there are huge moral and ethical questions about collection, storage, sharing and use of these data, which must be done within robust frameworks that protect the patients and are undertaken with a fully informed consent of the patient, where relevant. Belgium is doing great work in this area, building knowledge of general population and thus creating confidence in genomics at this revolutionary time in healthcare. We do of course need to make sure that legal frameworks also do not frustrate the need for scientists to keep finding new disease cures and better drugs and treatments.

Lest we forget, Europe's medical Ethics Committees came as a direct result of the post-World War Two Nuremberg Trials. If I recall correctly, it was in May 1947, during the trials, that ten points emerged to define legitimate medical research. These made up the Nuremberg Code, which includes principles such as informed consent and absence of coercion. All the points were, and are, geared towards endorsing an experimental approach to medicine while protecting the patient.

Today we worry about how the likes of, for example, insurance companies could act in a prejudicial manner against someone with, say,

a family genetic make-up that could lead to deadly forms of breast cancer or some other serious disease.

And unscrupulous employers could also act in a prejudicial way with genetic knowledge of an employee, although we'd all like to think they wouldn't.

Overall, there is no doubt that there are real and present concerns among patients, clinicians and insurance professionals.

**DH:** But don't patients want to share their data?

**FDL:** Fortunately, Denis, surveys strongly suggest that most patients are happy to share their data for certain types of research - as long as trust is there. And the latter is a key, if not the key, aspect.

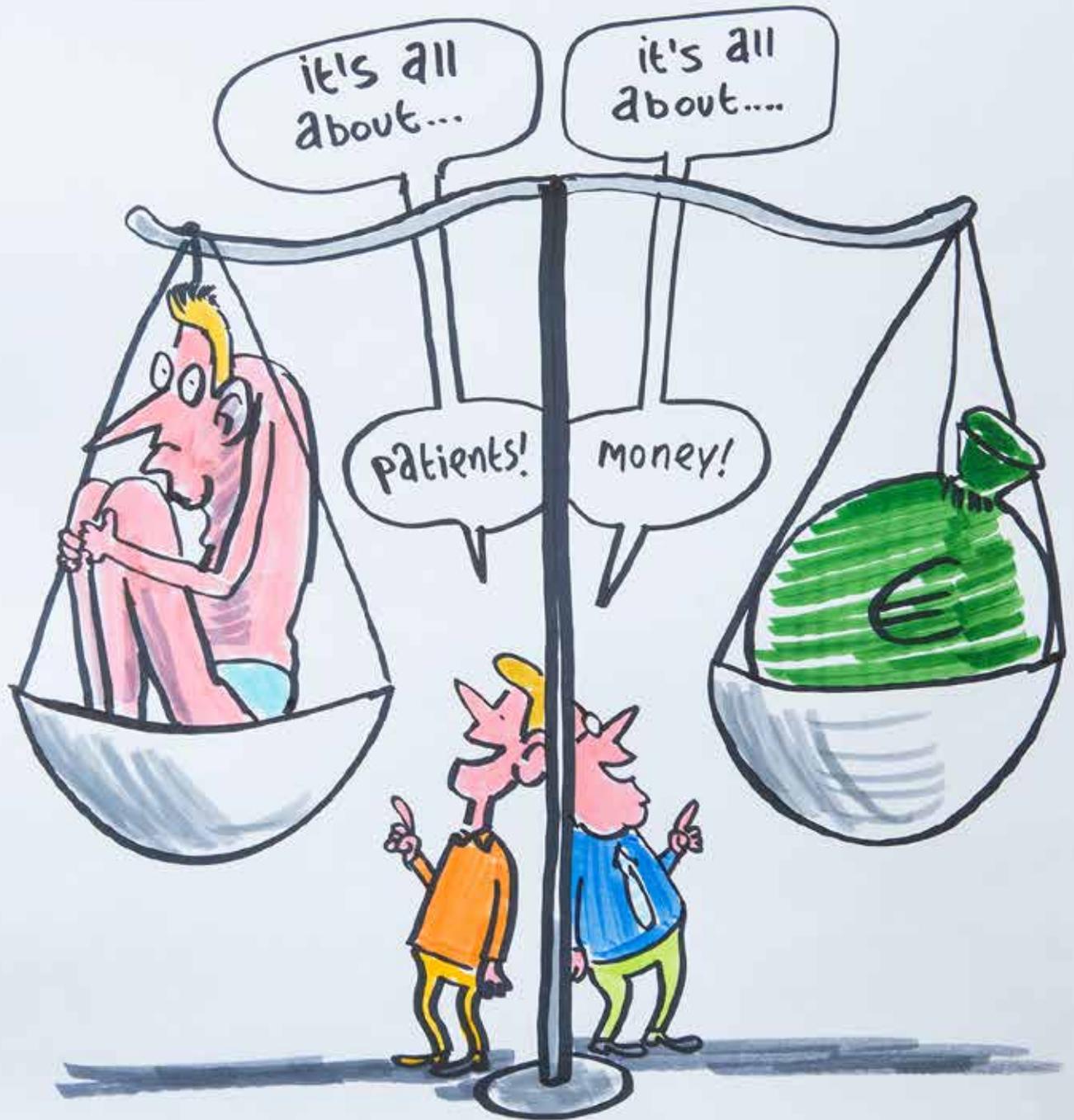
Recent estimates have suggested that there will be five million genomes sequenced worldwide by the year 2020. That's next year. These will have been sequenced primarily for research but will include a growing use of genomic sequencing and testing by healthcare providers or individuals. Unfortunately for the advancement of medicine, the concerns I've mentioned during our chat may cause some patients to avoid genome sequencing, even if it could benefit them. This would be a terrible shame and us, patient organisations and wider healthcare community have the duty to make sure that patients, should they make such a decision, would do so with full understanding.

So far, evidence suggests that the insurance industry is managing to self-regulate but, as data grows ever bigger and bigger, this is clearly a vital area that needs constant monitoring while, at the same time, the use of genomic data for medical research must be allowed to continue unabated.

There is no place for discrimination in healthcare, or anywhere else.

**BEST TREATMENTS  
IS IN OUR DNA**

# Different methods of weighing "value"



ComicHouse

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## WHY CUTTING-EDGE TOOLS ADD VALUE TO HEALTHCARE



Jasmina Koeva, Bulgaria  
Alliance for Personalised &  
Precision Medicine

**Specific IVD tests/companion diagnostics provide vital information to a medical professional regarding the likelihood of a patient responding to, or benefiting from, a certain treatment.**

**Earlier diagnosis and earlier treatment have many benefits, among them fiscal, because while cost is a major issue - and there are key questions about the cost-effectiveness of new and even existing treatments - better diagnostics will ease the burden on healthcare systems and lead to a healthier Europe.**

**Here, as part of a series of interviews for EAPM, the Alliance's executive director Denis Horgan speaks to Jasmina Koeva chair of the board from the Bulgarian Alliance for Personalised & Precision Medicine about companion diagnostics, the concept of value and more.**

**DH:** Let's start with a bit of background on companion diagnostics...

**JK:** OK, well these are complex but critical for the appropriate prescription of personalised therapies. They help doctors and patients choose or reject a treatment and help with the decision between several therapeutic strategies.

These diagnostics tests are vital when it comes to knowing whether a treatment is going to work for you or me or not. Why waste time and money giving me - or anyone else - a drug that is not right for me when it is possible to find one that is? There is no value there, any way you look at it.

Ongoing research and development of new therapies, diagnostic tools, and mobile technologies offer new opportunities, bringing faster and more accurate diagnosis, allowing patients to go home sooner, helping healthcare professionals to monitor conditions more accurately, and improving patient outcomes.

**DH:** Are you in favour of personalised, targeted medicine, then?

**JK:** Of course. By giving the right treatment to the right patient at the right time,

personalised medicine is crucial in this context. It's a lot about confidently and scientifically identifying patients who have the best possibility of having a positive response to a given treatment. Companion diagnostics really help to make sure that patient data can be used to allow better choices.

We are talking here about a more favourable risk-benefit ratio, which gives us better health outcomes, better quality of life, and better use of healthcare resources which, as we all know, are under pressure.

Then there's the fact that safe companion diagnostic also help reduce the number of adverse events linked to medicines because they help to predict which patients may have increased risk and/or serious side effects, as well as those who would be non-responsive. It's all about making more informed decisions, which is a key value in itself.

**DH:** So, it's more patient-centric?

**JK:** Absolutely. By helping to reduce some of the uncertainty around treatment, these complex tests are unique even within the field of in vitro diagnostics, or IVDs.

They are enormously helpful in shifting health systems from a treatment-centred approach to a truly patient-centric one.

I know from my work that patients are overwhelmingly in favour of the use of cutting-edge companion diagnostics that can tell them what diseases they have, and the best way to treat them, while payers and lawmakers are much more cautious when weighing cost against 'value'.

It is unfortunate, but the inherent value of such tools and tests is perceived differently by different stakeholders.

**DH:** For example?

**JK:** Well, for sure the value that comes from choosing the right treatment, as well as that which stems from not choosing the

wrong treatment, should be accounted for when funding or reimbursement issues are considered in the overall diagnostic-treatment package.

Also, recognition of the role of companion diagnostics in personalised care is necessary to strengthen EU approaches to this style of healthcare and in developing a cohesive approach that cuts down on inequalities and boosts patient access.

But as well as recognition, we need practical acknowledgements too. These need to become apparent in the regulatory framework, as well as in pricing and reimbursement systems.

In my view, information provided by a companion diagnostic test is valuable in its own right and not just in its relationship to a specific treatment.

This is particularly true in instances where the test results indicate that treatment could harm the patient, or where the companion drug is found to be inappropriate, as I've mentioned.

**DH:** In an EAPM survey we found that 96% of patient respondents said they would be 'interested' or 'very interested' in having a companion diagnostic available for them. What does that show?

**JK:** Obviously it is clear that patients place significant value on having the facts. And I should add that there are also considerations and characteristics of a companion diagnostic test that patients would like to see health systems and insurers consider in light of the diagnostic value.

For both the patient and the cost-effectiveness of healthcare systems, payers should focus on prevention as a long-term investment, not a short-term cost, one that has the potential to enhance quality of life. There is a model called VODI, which stands for value of diagnostic information, and its

approach toward assessment is by way of considering the expected value as relative to the expected cost and the value in relation to the reduction of uncertainty.

This can be estimated as a cost-saving stemming from reducing inappropriate treatment decisions.

Myself and many others believe that the VODI approach allows for a more optimal access model for patients, while improving efficiencies for assessment.

Personalised healthcare is not just about saving lives, but also improving them, and putting a substantial value on diagnostic information will help to realise these goals and create a healthier and wealthier Europe for us all, now and down the line.

**PURE GENE-IOUS**

personalised medicine  
is all about the patient

now.....

What pill for  
what patient?.....

YOU are going to need  
— some medicine when you  
Give me the blue  
one....



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# INNOVATION, ACCESS AND PREVENTION

## A PATIENT'S HOLY TRINITY



Barbara Moss,  
EuropaColon

**This next interview sees EAPM's executive director Denis Horgan (DH) chat to patient advocate Barbara Moss (BM) about innovation, access and preventative healthcare.**

**Barbara Moss is a patient Ambassador for DiCE, EuropaColon and Bowel Cancer UK. She is also a Patient Advocate with Inspire2Live and is part of an Expert European Patient Advisory Committee called PAC. .**

**DH:** The European Parliament elections take place in May this year, as you know, so what are your hopes in terms of improved patient access to innovative treatments?

**BM:** Yes. It's a big year, with the elections you mention plus a new Commission in due course and, of course, whatever impact Brexit may have. Of course, this is of particular interest to me as access to a new drug is what saved my own life and why I want change for other patients. I was given a prognosis of only three months and here I am 12 years later!

Assuming Brexit goes ahead as scheduled, by May there will be 46 less seats in the EP which, depending on how you look at it, might make it easier to engage with them all. Not quite so much running around, Denis! Realistically, though, we all still have a tough but important job to do in letting the new intake know, across both institutions, that access to innovative medicines and treatments for the EU's patients is less than optimal and needs to improve.

Those MEPs who are already in their seats and are up for re-election probably don't need reminding, but we'll do it anyway.

**DH:** So, what are the issues?

**BM:** Access is not the same across all Member States, and within regions of the same EU country, prices for new drugs are often so high that they are inaccessible for healthcare services - whose idea of 'value' is often not the same as that of patients - and there are too few incentives for companies to innovate knowing they have to get their money back, somehow.

On top of this, smaller-scale clinical trials are difficult to run as it is a logistical struggle to get those with rare diseases together across many Member States, cross-border healthcare is not working as well as it was envisaged, training for healthcare professionals in the new aspects, such as targeted treatments, needs to be upscaled quickly, and the sharing of healthcare data needs to be boosted substantially.

Other than those items, there's not much to worry about...

**DH:** OK, plenty going on, then. What can policymakers do at any or all levels?

**BM:** From an EU perspective, only so much, given Member State competence for healthcare, although you can't fault the Commission for trying, really.

In this huge arena, it has produced overarching legislation on in vitro diagnostics, clinical trials, data protection etcetera and is now working on joint action on health technology assessment. The latter should make access easier, as and when member countries can agree the way forward. But still we have the access conundrum.

As you know, Denis, access to optimal healthcare is of serious concern to an ageing population now suffering, in a growing number, from more than one disease. Meanwhile, the rare diseases that I mentioned earlier are being discovered all the time,

without optimal ways to deal with them. We are also beginning to realise that every cancer, when diagnosed, could be considered rare as it is specific to that patient's DNA! To be fair to them, we know that our policymakers want to support improved access and no-one said it is easy. Different mechanisms are currently coming under the microscope, such as the supplementary protection certificate, or SPC, waiver currently under discussion in Council. Meanwhile governments are having to tackle regular shortages of medicines, which vary from Member State to Member State but are clearly a problem, according to pharmacists up and down the EU. The UK is particularly worried about this in a worst-case post-Brexit scenario.

And all stakeholders need to look out for, and cut down on, wasteful healthcare, including over treatment, spending in Europe. We need to start to be smart, at all levels of policymaking.

Evidence has shown that countries actively managing rational use have lower spending growth for medicines as a whole, and therefore more potential headroom for innovation.

**DH:** Any broad solutions?

**BM:** Plenty have been put forward but there are so many elements involved, as mentioned. For example, proposed solutions to improve access range from better coordination and collaboration models between stakeholders and decision makers at various stages within the bench-to-bedside timeframe, to more sophisticated pricing, reimbursement and funding mechanisms..

We also need more effective forms of utilisation management to address the inherent complexity of personalised medicine. As I've touched upon, innovation and the incentives for this, are vital to health and wealth in the current EU-28, and will be even more important after the UK leaves. It also

encourages investment from outside of the EU, clearly good for business and jobs. When put together in a proper joined-up way, these aspects will certainly contribute to better access for patients to the best new treatments.

**DH:** What about Member States' role in particular?

**BM:** Well, as noted, the EU can't act alone. All Member States have to adapt, take a look at their HTA and approval procedures, which is ongoing as mentioned, and certainly collaborate much more with their fellow countries across borders in many spheres. This obviously includes the sharing of knowledge and research, and the pooling of Big Data.

It is also evident that the Member States, in tandem with the EU, need to ensure the proper transposition of legislation and policies regulation at national level. This doesn't always happen as well as it should. Generally speaking, more work needs to be done on agreeing treatment guidelines, and encouraging their implementation, quickly and effectively. We need strategies in place in order to deliver fair treatment for all. All Member States come at healthcare from a different angle. Sometimes this is due to wealth or lack of it, a high or, indeed low, incidence of a particular disease or diseases in its population, the cost of pharmaceuticals, cross-border payments to patients, the strength or otherwise of patient advocacy and more. There are often many differences, even within the regions of the larger nations, as I suggested earlier.

Member States policymakers need to be clear that innovation is key to progress and the translation of research is another key issue. This affects both treatment, once a disease has been discovered, and importantly, prevention, with all the cost savings that go

along with the latter. Patients often value most highly continuation of the best quality of life.

**DH:** You mention prevention. Elaborate, please...

**BM:** Well, I'm hardly being original when I say that prevention is better than cure. Personalised medicine, for its part, tends to focus on targeted treatment but, in general, prevention is vitally important, especially with cash-strapped healthcare systems. While we all want to deliver the right treatment for the right patient at the right time, we also want and need the right preventative measures to ensure reliable and sustainable healthcare. I don't want to sound too dramatic but, currently in Europe, not only are patients failing to receive the best care, there is potential to cause them preventable harm.

**DH:** So, what would you suggest?

**BM:** It's clear that investment is required in diagnostic approaches, such as the use of IVDs and more screening, certainly in lung cancer. Just to elaborate on the latter for a moment... Comprehensive screening programmes have been in place for some time for several other cancers, but not so for lung cancer. Especially in the wake of the NELSON trial results, this is a little crazy given that it is the biggest cancer killer of all. It is such a huge killer partly because it is harder to detect in its early stages. By the time a person begins to notice symptoms, it has often spread to other parts of the body and is, therefore, difficult to treat.

The majority of lung cancers in both sexes are caused by smoking, but about 15% are not, and the majority of those non-smokers are women, mostly young women. But it is not just lung cancer, of course. Breast cancer and prostate cancer, for

example, are curable in the early stages in many cases. It's often all about catching the disease early. And that's the lion's share of prevention.

Also, educating our citizens in the dangers of obesity and related issues such as a lack of exercise and an unhealthy diet, smoking, alcohol abuse and so on is an important part of prevention. More and more we are finding that lifestyle is a major factor in, say, diabetes and its many associated illnesses, so education is a key tool.

So here, there are a few examples of prevention.

**DH:** Can you tell us more about screening and education?

**BM:** Yes. Screening in various cancers has proven successful and, lest we forget, new breakthroughs in genetics are allowing doctors and other clinical experts across many disciplines, the chance to much-more accurately predict the potential onset of a disease in an individual. We are gaining knowledge of the best way to treat the disease at an early stage.

To make the most of this, it's not just the patients and potential patients that we need to educate, we also need up-to-the-minute education for healthcare professionals in this brave new world in which personalised medicine is a game changer.

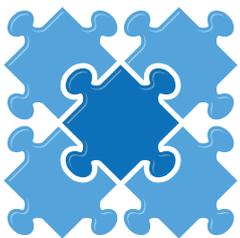
And I mentioned guidelines earlier. Well-informed healthcare professionals and unified guidelines will play a key role in harmonising care.

Fortunately, treatment and medicine is moving from health professional-led decision making to evidence-based shared decision making, and a number of European guidelines have been developed in specific disease areas, such as in urology, respiratory medicine, gastroenterology and cardiology. But it is still important to address the major gap in engagement between the scientific

community and key stakeholders as users and beneficiaries of guidelines. Collaboration is the key.

Essentially, work needs to continue in all areas to agree and publicise guidelines in the complex and developing world of personalised medicine and to diagnose illnesses early on. This is key to prevention. We need consensus on strategies. The work on these matters and on access needs to continue and move forward rapidly when the two newly formed institutions start working together.

Knowledge, through research, on personalised medicine, on prevention and care is moving forward so rapidly. We must ensure that those making decisions on our lives take the responsibility to move quickly. The work on this and access needs to continue and be boosted when the two newly formed institutions sit down and start to do their work.



## European Alliance for Personalised Medicine

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