



# European Alliance for Personalised Medicine

EAPM Bulletin: Issue 55, October 2019

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## Key events for EAPM and Ursula's new team

Welcome to EAPM's October newsletter. It's a month that promises to be a busy one for **Ursula von der Leyen**, the Commission President-designate, and quite possibly for British Prime Minister **Boris Johnson**, now that he's had his wrists well and truly slapped by the highest UK court for knowingly misleading his own monarch.

With Brexit still in the balance, British MPs as well as House of Lords peers will be back at work today after the Supreme Court ruled that proroguing Parliament was unlawful.

Premier Johnson returned early from a UN summit in New York, while the opposition Labour party cut its own conference short, following the unanimous ruling by 11 judges.

Johnson has said he "profoundly disagreed" with the decision but would respect it, while Speaker **John Bercow** won't call on him for Prime Minister's Questions, today at least.

Aside from all that, here's a preview of the high-level roundtable to be hosted by the Alliance as a satellite event at this year's **ESMO Congress**, held in Barcelona.

For the 7th year in succession, EAPM will be present at the prestigious event and, for the fourth time, will be holding its own meeting, with the focus on bringing innovation into Europe's healthcare systems.

The drivers of personalised medicine are clear: for patients (and physicians) – more options, durable clinical benefit, reduced exposure to non-effective drugs and potential to leverage current scientific and technological advances.

For the pharmaceutical and molecular diagnostics industry there's the potential to tackle core challenges in discovering and developing more effective medicines, to reduce rates of attrition in drug development, and to reduce the associated escalating costs which are central to a more sustainable future and delivery for healthcare needs.

Meanwhile, for healthcare systems and payers – improved efficiency through the provision of efficacious and cost-effective care through the avoidance of ineffective and redundant interventions, are again key to a more sustainable and deliverable future system.

The roundtable will hear that diagnostic and therapeutic innovation must be implemented in a structured cost-effective approach that emphasises measurable improvements in outcome for the patient in the personalised healthcare era.

### In the EAPM pipeline:

- **8 October: MEP Roundtable, Brussels**
- **24-25 October: Second Balkan Conference on Personalised Medicine, Sofia**
- **3-4 December: EAPM 3rd annual Congress, University Foundation, Brussels**

Resourcing and pricing issues must be addressed in a tangible and transparent fashion to ensure best value in the delivery of optimal quality care for patients.

What is abundantly clear is the urgent need to address the cost/value axis associated with personalised healthcare and develop financially viable but effective solutions.

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

The sessions will be on the following over-arching topics:

- *Oncology and real-world evidence*
- *Putting personalised medicine into practice: the value of prognostic testing for breast cancer and prostate cancer in Europe*
- *Biomarkers - EU Policy recommendations for patient access to high-quality testing and molecular diagnostics*
- *Translating policy into practice - The value of personalised medicine for public health, its impact on EU health policy, and its global dimension*

In order to provide a clear focus and to devote sufficient space to analysis, discussions during the event will concentrate on how:

- *To assess and address obstacles to the integration of personalised healthcare into Europe's healthcare systems*
- *To identify best practices and their added value*



● To outline the potential benefits of personalised medicine on public health and its impact on policymaking in the EU

Each session will comprise panel discussions as well as Q&A sections to allow best possible involvement of all participants.

Said EAPM executive director **Denis Horgan** ahead of the event: "This is certain to be an excellent meeting with all of the key stakeholders, and at one of the most prestigious medical Congresses in Europe.

"We are delighted to be able to host the event in Barcelona and we expect to move forward with the messages that are certain to emerge from what is very much a working meeting.

"As ever, we will be urging all delegates to actively contribute."

## Meet-up in Milan

Big Data, electronic health records and health governance were all on the agenda of a workshop attended by EAPM in Milan just prior to the ESMO event.

Denis chaired a session attended by the Director-General of the Regional Minister of Welfare, **Luigi Cajazzo**.

The aim of the event was to explore one of the key themes of the **Regions4Permed** project, which is understanding how Big Data and digitalisation can support measures to promote health, as well as to reform health systems, easing the transition to new patient-centred care models, and to new integrated care structures.

On the table was the potential, the risks and role that regions can play in the governance process of health data, focusing in particular on where we stand now, and the next challenges.

There were four key policy areas:

● *Data integration and interoperability*

● *Investments in Big Data infrastructures*

● *Healthcare organisations in a changing environment*

● *Promoting access to data*

The key conclusions of the workshop will be made available to stakeholders shortly.

## EAPM October meetings

The Alliance is organising a roundtable on 8 October in the European Parliament.

Said Horgan: "Of course, we'll be walking the hallways to the MEPs' offices long before the meeting, but this roundtable in early October obviously comes at an important time."

"Topics up for discussion will include time given our planned, ongoing engagement with certain new commissioners," he explained.

He went on to emphasise that the crucial topics on the table will include realising the potential in the declaration of cooperation for the One Million Genomes project, with a focus on the issues relating to real-world evidence.

Also up for discussion will be cancer and rare diseases, with a specific focus on lung and prostate cancers, in terms of early diagnosis.

Linked to the above will be the subject of molecular diagnostics and biomarkers with a view to formulating a workable framework to facilitate their optimal use, and what Denis describes as "positioning EU leadership in the area of personalised healthcare". AI is also on the table for the gathering.

Later in the month, in **Sofia**, EAPM will once again be collaborating with the **Bulgarian Alliance for Precision and Personalized Medicine** (BAPPM) for a Second Balkan Conference on Personalised Medicine.





## **Would-be Commissioners under scrutiny in October:**

**Above-left, Poland's Janusz Wojciechowski; above-right Hungary's László Trócsányi and, left, Rovana Plumb of Romania**



This will take place from 24-25 October, and will be co-hosted by the Medical University Pleven and the Bulgarian Society of Human Genetics and Genomics.

The topics covered across the two days come under the banner *Forward Together in the Personalised Medicine Era*, which will look at the broad impact of personalised medicine, which promises to create a new paradigm in healthcare.

Also covered will be *Genomics for Healthcare*, looking at new achievements in human genomics and genetics alongside gene therapy, as well as the European genomic initiative "1+MG".

A further session on *The Pathology of Personalised Medicine* will look at *molecular pathology* - specifically at new achievements and implementation in clinical practice - as well as *precision imaging* in modern-day healthcare.

On Friday, 25 October, a further plenary session will look at personalised medicine in oncology and hematology, and cover screening, targeted and combined therapy, plus adjuvant and neo-adjuvant therapy.

Also covered will be immunotherapy, radiotherapy, the monitoring of lung cancer, as well as colon cancer, prostate cancer, melanoma, pancreatic cancer, and head and neck cancer.

Personalised medicine and rare diseases and personalised medicine in endocrinology will also get their time in the Sofia spotlight while the conference will bring virus infections, neurology and psychiatry into focus in a personalised medicine context.

## Von der Leyen Commission latest

While, as mentioned at the top of this newsletter, the UK's Supreme Court has announced its ruling in respect of whether Boris Johnson misled **The Queen** over the proroguing of Parliament, the Ursula von der Leyen team of would-be Commissioners await their turn for a grilling by MEPs.

The European Parliament currently plans to hold two hearings

on 30 September, six on 1 October, another six on both 2 and 3 October, and three on 7 October.

The three proposed Commission executive vice-presidents will take their turns on 8 October, with the final vote on the entire Commission planned for 23 October.

As well as facing tough questioning from deputies, von der Leyen and some candidates could also be questioned by law enforcement authorities and parliamentary committees undertaking investigations. It's generally thought that not every candidate will survive the process (we're talking about **Rovana Plumb** (Romania), Poland's **Janusz Wojciechowski** and Hungary's **László Trócsányi**).

Even without such looming shadows, the hurdles for commissioners-designate to vault over are high. European Parliament rules require a majority of at least two thirds among the most influential MEPs, which means the political groups' committee coordinators, for an immediate 'pass'.

The rules state that: "If coordinators cannot reach a majority of at least two-thirds of the committee membership to approve the candidate", he or she must answer additional questions in written form or reappear before the committee. If a two-thirds majority is still not reached, a simple majority in a full committee vote would usually suffice.

Meanwhile, Denmark's **Margrethe Vestager** is in charge of "a Europe fit for the digital age", which means she has plenty to oversee, not least in the realm of the sharing of important medical data in the personalised medicine age, including genomes exchanges and, of course, e-health records.

Elevating three executive vice-presidents from an eight-strong group of VPs is without doubt the biggest structural change that von der Leyen announced in September, at the same time as describing her Commission as a "geopolitical" one.

As one commissioner-designate put it (**Valdis Dombrovskis**, who is a former prime minister of Latvia), the incoming Commission aims "to be leaders rather than followers" in light of





an expected “radical transformation” of EU economies and societies.

Incoming Health Commissioner **Stella Kyriakides** (Cyprus) has already, we’re happy to note, emphasised priorities including the supply of affordable medicines, the implementation of the new medical devices regulation, and the creation of a European Health Data Space.

She also highlighted antimicrobial resistance, vaccination and a European plan to beat cancer.

As promised, vdL has tasked Kyriakides with formulating the cancer plan, which would support Member States in improving prevention and care.

Meantime, Bulgarian Commissioner **Mariya Gabriel** will take the innovation and youth portfolio for her second stint in the Berlaymont. This covers research policy and the Horizon Europe programme.

Going back to Vestager, it has emerged that the Commission’s digital department has advised her and **Sylvie Goulard**, the internal market commissioner-designate, to focus on artificial intelligence (AI), the Digital Services Act, greening technology and enhancing Europe’s technological sovereignty as priorities for legislation.

It is thought that staff at DG CONNECT will work with those at DG GROW, DG JUST and DG SANTE.

There seem to be a not-very-surprising emphasis on high-risk applications, which certainly includes using AI in cases where it could influence life-or-death healthcare decisions.

## Orphan drugs and commitments on cancer

Soon-to-depart Health Commissioner **Vytenis Andriukaitis** gave the European Parliament the news that the evaluation of the orphan drugs and paediatrics regulations should be published at the beginning of 2020.

This during its cancer debate in September in Strasbourg.

During the debate, MEPs united to call for more European cooperation on fighting cancer at all levels. That means from politicians, to researchers and doctors.

**Manfred Weber**, the one-time *Spitzenkandidat* for the EPP group who stood on a fight-against-cancer platform, told the gathering of deputies in Strasbourg that 40% of Europeans will experience cancer and that, every second, a cancer patient dies.

Three-quarters of Europeans have called for combatting cancer to be a top issue for the EU, and the EPP has called for the establishment of a special EP committee to fight cancer.

Commissioner Andriukaitis said that the next Commission would focus on fighting cancer at all levels, including its causes. The current Finnish Presidency of the EU, meanwhile, noted the role of the economy of wellbeing in the fight against cancer.

**Tytti Tuppurainen**, Finland’s Minister for European Affairs, said that the debate came at the right point in time given that cancer is on course to become the leading cause of death in most EU countries.

She added that research also shows that high mortality is not necessarily related to risk factors but could be related to access to healthcare. All EU citizens should be able to live a healthy life, the minister stressed, and have equal access to healthcare.

With such high goals, close collaboration between institutions, stakeholders and sectors is needed, the MEPs heard.

Given the EU-wide agreement that cancer should be a priority, Europe requires research, access to medicines and screening to push the agenda.

Minister Tuppurainen said that the Council and Parliament has agreed to include cancer research under the Horizon Europe framework, which will improve treatment and allow Member States to better tailor their public health interventions.

Commissioner Andriukaitis, who has lost three brothers to cancer, said that Europe needs to put its money on remedies that are not only from a doctor or the health commissioner.



These, he said, are political questions, including risk factors and determinants, both social and political.

He noted that Commission President-elect Ursula von der Leyen's letter to her proposed Commissioner for Health, Kyriakides, focuses on ways to ensure that Europe will have affordable medicines, and said he is pleased that the cancer plan has been included in the political priorities of the new president.

The EPP's **Ewa Kopacz** called for new incentives for research. Cooperation between academic centres is also required, as is cooperation and exchange of best practice, she insisted.

The Polish MEP said that everyone should work above party lines to set up a special committee on cancer. This would be possible under Article 207 of the European Parliament's Rules of Procedure, she said.

S&D MEP **Sara Cerdas** pointed out that cancer has an impact both on health systems and on the EU economy, adding that cases could be reduced by more preventive strategies. The Portuguese deputy also called for support for scientific research to underpin any new decisions with the best information.

Cancer specialist **Véronique Trillet-Lenoir**, of the Renew Europe group, said that cancer medicines have to be available at a reasonable price, while more funding is required as part of Horizon Europe.

The French MEP underlined that cancer is also a social injustice, due to inequalities in terms of prevention, the speed of diagnosis and treatment.

Green deputy **Michèle Rivasi** said that Europe is witnessing an increase in chronic diseases, noting that there could be a doubling of cancer patients by 2025,

And the EPP's **Dubravka Šuica** (Page 5) felt that there were no political differences on the topic of cancer, and praised the work of the current Commission while hoping that its successor would invest in research to enable access to medicines.

MEP **Elena Kountoura** told the gathering that breast cancer kills more women worldwide than any other cancer. If diagnosed in good time, breast cancer is 100% treatable, she said.

She called for programmes and awareness raising to be put at the front line to ensure that all patients have access to treatment. Meanwhile, French MEP **Chrysoula Zacharopoulou** highlighted that cervical cancer is one of the deadliest of cancers. A great number of women die from it but, thanks to vaccination, women can be saved.

Renew Europe's **Susana Solís Pérez** said that research and innovation are vitally important. Here, the Spanish MEP said, is where Parliament plays a key role. It can demand that Horizon Europe should have enough money for researchers.

She added that EU institutions are working together to ensure that researchers have all the resources that they need.

Minister Tuppurainen wound up the debate, by reiterating that cancer is a tragedy at the personal level. It is a fight that can be lost, despite all efforts of will and the best help available. Therefore, the EU should use every tool available to it.

## Survival rates on the up

And while we're talking about cancer, survival rates appear to have improved over the past 20 years in some developed countries, including three currently in the EU.

The report from the *International Agency for Research on Cancer*, which collected data on 3.9 million patients in Denmark, Ireland, the UK, Norway, Australia, Canada and New Zealand for seven types of cancer, looked at one-year and five-year survival rates across two intervals, 1995-99 and 2010-14.

The cancers studied were oesophagus, stomach, colon, rectum, pancreas, lung, and ovary, and the report states that: "Over 1995-2014, one-year and five-year net survival increased in each country across almost all cancer types." It adds that five-year rectal cancer survival increased more than 13% in Denmark, Ireland and the UK.

The research agency said that the improvements probably resulted from major healthcare reforms and technological advances that have enabled earlier diagnosis, plus more effective and tailored treatment, as well as better patient management than before.

In the wake of the report, Ireland's Health Minister **Simon Harris** (pictured above) said that cancer prevention is the most



cost-effective way to control the disease, adding that he's set to put forward new tobacco controls in the not-too-distant future.

## ENVI's health challenges

*Eurobarometer* surveys show health as a main concern and an area in which the EU has been asked to do more by citizens. Nearly 10% of the EU's GDP is spent on healthcare while, despite gains in life expectancy, Europeans on average spend between almost a quarter and a fifth of their lives with a disability.

More than 1.2 million people in the EU died from illnesses and injuries in 2013 that might have been avoided, while the burden of ill-health and premature mortality falls disproportionately on people exposed to socio-economic vulnerabilities.

A number of public health-relevant procedures that are currently in progress and assigned to the ENVI committee - such as developing an ethics-based digital future and enhancing the inclusiveness and integrity of policymaking - are closely linked to public health challenges.

An EU Mission Letter describes several priorities, among them tackling vaccine hesitancy alongside ensuring the effective and future-oriented implementation of the medical devices regulations.

The Mission Letter calls for making use of opportunities offered by e-health and prioritises the creation of a European Health Data Space. Different challenges in this space remain to be addressed, such as the ethical and equity implications of digitalisation, m-health, data privacy and ownership,

Meanwhile, artificial Intelligence, digital marketing, and the wider implications of digitalisation for health systems, including the evolution of personalised medicine are key priorities going forward.

On top of this, Europe's role on international trade and investment agreements and the EU's approach to global health may provide significant added value for public health.

The same applies to ensuring adequate funding allocations in the EU budget for the effective pursuit of health and health-equity objectives.

## More health for parliament

In respect of digital health, an oral question to the Commission on a Parliament resolution on the digital transformation of health and care is set to be re-tabled.

By all accounts, the text of the resolution from the previous legislature will be slightly reviewed, with the MEPs now in charge of it being Poland's **Bartosz Arłukowicz**, the aforementioned Sara Cerdas, Belgium's **Frédérique Ries**, Italy's **Luisa Regimenti** and **Anja Hazekamp** of The Netherlands - that's, according to an ENVI planning document.

Meanwhile, an oral question and resolution on the EU's strategic pharmaceuticals in the environment is also on the way.

In this case, the MEPs involved are Austria's **Sidl Günther**, the Netherlands' **Jan Huitema**, Italy's **Simona Baldassarre**, France's Michèle Rivasi (whom we've already mentioned), Poland's **Joanna Kopcińska** and the Czech Republic's **Kateřina Konečná**.

## HTA latest

The whole issue over health technology assessment continues. As you may recall, the European Commission's amended plans are now at Council level, and Germany's Health Minister **Jens Spahn** has had a couple of things to say about progress.

Spahn (above) was talking to *Politico* in September and revealed that, despite objections to perceived Commission



over-reach led by his country and the other big-hitters France (Berlin and Paris object to mandatory HTA uptake, emphasising Member State competence) he feels that a solution is possible.

He added and that Germany still has “good talks with our EU partners”.

In more detail, Spahn was reported as saying: “I’m convinced that science should not lead to different results in Madrid, Warsaw or Copenhagen. That’s why we can make health technology evaluation more European.

“But we have to answer at the national level the question of what consequences this evaluation has for each respective national health system.”

The health minister wants to “proceed cautiously”. He said that: “All sides still have to learn about European benefit assessment. It’s about building confidence in this new method. So why not evaluate only ten medicinal products per year using the new method? Then we can look ahead.

“One thing remains clear to me: Each EU country must draw its own conclusions from a European benefit assessment. Social security is a national competence. I don’t want to give up on this principle.”

Spahn added that he hopes “the new Commission will be a little more willing to compromise”.

## Germany's health priorities

Lest we forget, Germany takes over the rotating EU Presidency in mid-2020, and Berlin’s health supremo highlighted digitisation, Big Data and artificial intelligence as core priorities for his portfolio.

He said during an interview that “we should concentrate on those areas that actually generate added benefit for Europe. These are cross-border issues such as infectious diseases, patient mobility and the supply of medicines”.

Spahn, is a compatriot of Commission President-elect Ursula von der Leyen, and one of a bunch of hopefuls vying to succeed **Angela Merkel** (pictured) as German chancellor.

His message for the incoming European Commission runs thus: “Instead of just ‘we should do it’ speeches, it should be ‘we are doing it’, less describing problems, more solving problems.”

He said he wants von der Leyen - whom he calls “fast, structured and ambitious” - to have a big effect on the way the EU goes about its business.

“Europe needs ambition and ideas, but Europeans also want solutions that improve their everyday lives,” Spahn said.

## Medical device manoeuvres

The EU’s Medical Device Regulation enters into force on 26 May 2020, although there have been well-documented concerns over readiness in certain quarters. Now we have the case of so-called Class 1 medical devices that will, for the first time, require their own safety checks.



Apparently, such devices were overlooked by the Commission when the regulation was written - oops! - but the executive has given the go ahead to include them, with the Council expected to initiate the procedure this month. It must also be agreed by Parliament.

The incoming regulation already permits certain medical devices to stay on the market until 2024, if certified under the previous rules. Now, this could be extended to devices that have been “up-classified” for the first time.

Germany and Ireland have led the line in wanting to address concerns that widely used products would become unavailable.

The US, meanwhile, wants the Commission to change the deadline, but it says it won’t.

One EU official, who played-down fears about the fact that, under the new regs, there will be fewer notified bodies that test devices, said: “This is the purpose of the regulation, even if we get less [notified bodies designated, that] is because we want only notified bodies which are up to standards.

“This is why we have the new regulation in place, because we want to provide better reliability and protection of safety.”

Some notified bodies have said they will not look to become compliant under the new regulation, with the official conceding that more may still withdraw.

Despite this, the Commission still plans to have 20 notified bodies approved to operate this year.

## Dutch queuing for care homes

In The Netherlands, the elderly are urgently queueing up for care home slots in ever-increasing numbers. The country’s ‘oldies but goodies’ formed a waiting list 14,000 strong in July, as they look for a spot near their homes.





The country's National Health Care Institute says that the number shows an increase of around 1,000 since February, with some 4,000 having been on the list for more than six months.

The Institute points to a shortage of nursing staff and, of course, a growing elderly population as key reasons.

## EAPM December Congress

EAPM will be following all relevant topics at its **3rd Annual Congress on 3-4 December**, which is to be held at the University Foundation in Brussels this year.

The Belgian capital has been chosen to host the event as the new Parliament is of course now in place, while the next European Commission will also, by then, be in the Berlaymont under its new president.

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

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

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

Online registration for the December congress will open this month (October), so watch the EAPM space!



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## About EAPM

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

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

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

**The mix of EAPM members and its broader outreach provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry.**

**Relevant departments of the European Commission have observer status, as does the EMA, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.**

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