



European Alliance for Personalised Medicine

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Weathering the storms and moving on...

Welcome to February's newsletter, which comes on the back of some pretty harsh weather across parts of Europe. Even Brussels had a snowfall that actually hung around for a while, and that's rare.

What isn't rare, of course, is that the year got off to a busy start with respect to EAPM and its stakeholders. And it shows no signs of slowing down in February and beyond.

Below are highlights and updates of issues that EAPM will be following closely and engaging with going forward.

In fact, stakeholders will be hearing regularly from the Alliance in respect of all activities in these areas.

Brexit - on or off?

Looming large still is the undecided issue of Brexit. And what a shambles that has proven itself to be already, while we're not even into the end-game, yet.

With all the in-fighting going on between parties, and factions within parties, there seems to be little real acknowledgement in the House of Commons of the upcoming consequences - especially if the UK crashes out of the EU with no deal.

The bottom line is that, if the UK leaves in such circumstances, there will be issues from Day 1 - and many more down the line.

Medicine shortages, a lack of warehouse space, chaos at customs points, more uncertainty among EU citizens in the UK and vice-versa, extra visa costs, skilled-staff shortages and student shortages, a loss of structural funds across regions, and possibly even grounded aircraft.

Far from being elements of a largely fabricated 'Project Fear', these are clear and present dangers.

At this stage, with the European Parliament elections looming in May, it may well be the case that Britain asks for an extension to Article 50. This may also see the UK fielding potential MEPs again when, in fact, the Parliament was due to set aside 46 of Britain's seats this time around, redistributing the other 27.

Nobody knows how it will all end. But what we *do* know is that the repercussions will be felt whatever happens.

In the pipeline:

- 8-9 April: EAPM 7th annual presidency conference, Brussels
- 19-22 June: 4th annual Summer School for HCPs, Leuven
- 18-20 November: EAPM 3rd annual Congress, Brussels

In other UK news...

It seems that some 40% of the nation's cancer patients have been originally misdiagnosed, often more than once.

And a study also found that 12% of UK patients are paying for some or all of their treatment themselves.

This is in order to avoid excessive waiting time or to get treatments that aren't covered by the NHS. Tough times look to be ahead...

Meanwhile, Britain has floated a new law to give pharmacists the authority to dispense different treatments from a doctor's prescription. Called the Serious Shortage Protocol, it will only apply in the event that certain medicines are in short supply.

Keith Ridge, NHS England's chief pharmaceutical officer, has written to all pharmacists saying: "Any protocol will be developed with input from clinicians and could cover dispensing a different quantity, pharmaceutical form, strength or a generic or therapeutic equivalent."

Ridge also ordered pharmacists not to stockpile medicines, on the basis that such actions could bring about shortages in other parts of the country.

However, stockpiling is undoubtedly happening, at the same time as some 10,000 ferry passengers have had their trips thrown overboard by Brittany Ferries to allow transportation of 'critical goods', post-Brexit, in the wake of "the government's initiatives to create additional ferry capacity".



eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

New presidency, new Commission to come

Not so long after the May European elections, a new Commission will fill the offices of the Berlaymont, which is yet another reason why it is more important than ever for the EAPM stakeholder group to get its key messages across.

We also now have a new six-month rotating presidency of the EU, namely Romania, which is already taking on various challenges and wrap-ups, not least concerning health technology assessment (HTA), medical devices, and an over-arching philosophy of cohesion as a common value.

As far as HTA goes, a compromise seems a long, long way away and it may be left to the Finnish presidency, which takes over in July, to finish the job.

In the meantime, EAPM will be continuously involved in the Million European Genomes Alliance - dubbed MEGA - as well as debates around lung-cancer screening, access, and bringing innovation into Europe's healthcare systems.

In all of these areas, we and our stakeholders will aim to garner the support of current and future MEPs through ongoing engagement and dialogue.

More on Romania

Towards the end of January, Romania's Minister of Health **Sorina Pintea** met with the Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) to underline her country's commitments in terms of public health.

These include promoting universal access to treatment for all those who need it, fighting antimicrobial resistance, improving vaccination coverage, reducing medication abuse and improving the control of transmissible diseases.

At the same time, Minister Pintea has made it clear that patient mobility will be a special topic of the Romanian Presidency, and among other things, an exchange of views will be held on the

application of patients' rights in cross-border healthcare. During the meeting the Minister also told ENVI that, in the field of health, the Presidency will continue to advance the EU agenda on topics that are important for European patients.

On HTA, she pointed out that health technology assessment is the only legislative file on the EPSCO Health Council agenda, adding that Romania wants to continue the negotiations as a priority.

Minister Pintea has said she is seeing the file as a "personal challenge" and also says she is convinced that patients and healthcare systems can benefit from closer cooperation in HTA. She did add, however, that Council is split on the application and consequences of enhanced cooperation, yet she insisted that all delegations are in favour of cooperation at EU level.

The minister, while appearing to accept that solving the issue is unlikely under Romania's watch, still feels that planned bilateral meetings with Member States may help to close the gap between the differing views of EU countries.

The European Social Insurance Platform, whose members include German statutory health insurance companies, has sent an open letter to Minister Pintea stating concerns that "the absence of legislation before 2020 could undermine the EU cooperation in HTA and the important work done for over a decade within EUnetHTA".

On access, Romanian MP **Antoneta Ioniță** has criticised her country's health ministry, medicines agency and national health insurance body because they didn't show up for a parliamentary debate on access to medicines and doctors.

In a press release she said: "We wanted all those involved and affected by the crisis of drugs and, in general, this poor state of the Romanian health system, to sit at the same table, to find viable and consistent solutions."

She added that the debate's conclusions will, irregardless, be presented to the health and finance ministries.

A background network diagram with nodes and connecting lines, transitioning from light blue in the top left to light orange in the bottom right.

EAPM

7th Annual Conference

BRUSSELS

8–9 April 2019

4th EAPM SUMMER SCHOOL

19–22 June 2019 // Leuven

EAPM

3rd Annual Congress

BRUSSELS

18–20 November 2019



HTA - the (latest) latest

German Health Minister **Jens Spahn** (above) announced that he wants to “help” around 3 million obese women with lipedema get access to liposuction through an amendment to existing law.

This has kicked off a debate about medical reimbursement decisions in Germany.

Lipedema is a chronic condition causing a build-up of fat cells in various parts of the body and Spahn told affected women: “We want to help you quickly and unbureaucratically.”

This flies in the face of the Federal Joint Committee, the independent body that decides what exactly Germany’s statutory health insurance will reimburse, which had come to the conclusion that there is “insufficient evidence” to reimburse liposuction for lipedema.

The committee’s chairman, **Josef Hecken**, said in a statement that Spahn’s parliamentary amendment amounts to overreach and would cause a “complete system breakdown”.

The opposition Social Democratic party will not back Spahn, with one of its MPs Karl Lauterbach saying on Twitter: “If soon ministers are deciding how things are treated and what is paid for, we will lose quality and money without any controls.”

And Greens MP **Maria Klein-Schmeink** said, also on Twitter, that the move would “open the floodgates to arbitrariness and lobbying influence”.

Now Minister Spahn may not have thought something else through. One of Germany’s objections to the Commission’s HTA proposal is to protect its own highly thought-of system, which the minister now seems willing to override. Oops.

Staying with the Federal Joint Committee’s Josef Hecken... In the context of orphan drugs, he has said that the current Commission proposal on HTA would not necessarily help speed the delivery of rare disease drugs to the market.

Hecken worries that an outcome, in which a single vote could make a difference, could lead to one “without the submission of any reliable evidence”.

“If this becomes the basis for a joint benefit assessment, this benefit assessment will not be worth anything,” added Hecken.

Finally on HTA this month, Lithuania’s health minister Aurelijus Veryga has said that amendments to the country’s pharmaceutical law would expand the ambitions of its HTA system, and draw on experience from other countries.

HTA in Lithuania would look at “financial benefits,” which include the “the number of hospitalisations, disability and nursing needs”.

Cross-border healthcare and the SPC waiver

Romania may surely note, as do we, that a non-binding resolution on cross-border healthcare has taken place.

It calls for the European Commission to “negotiate a solid agreement with post-Brexit UK on health, devoting specific attention to cross-border rights for patients and the functioning of the ERNs (European Reference Networks).”

The ENVI committee voted in favour of its own submission which looks at possible shortcomings to the implementation of the cross-border healthcare directive and makes recommendations to improve it.

The report examines funding for cross-border healthcare, patient mobility, patient information and access, as well as e-Health, interoperable healthcare applications and support for rare disease patients.

Meanwhile, the legal affairs committee in Parliament has backed amendments to the supplementary protection certificate (SPC) waiver.

The amendments allow for a two-year stockpiling (that word again) period for pharmaceutical generics. This is despite the fact that neither the Commission proposal nor the Council’s position has backed stockpiling.

The report still needs to be voted on by the full Parliament, but generics lobby Medicines for Europe has already called the move a “positive step forward”.



Meanwhile, Health Action International reacted by calling Parliament's position "A milestone in the ongoing process of assessing the effectiveness of intellectual property incentive mechanisms in promoting access and stimulating innovation."

IMI

The Innovative Medicines Initiative (IMI) is looking at its next lines of research, with a budget of €80 million.

Plans include building an open-access database hosting genetic information on the 1,000-3,000 genes thought to be potential targets for pharmaceuticals, as well as learning more about the potential risks that active pharmaceutical ingredients could pose to the environment.

Also mooted are personalised obesity treatments made possible by the identification of relevant subgroups of obese people. The emphasis here would be on diabetes.

Still with research, European Commissioner **Carlos Moedas** (above) has said researchers in healthcare should work harder at communicating the benefit of their projects to the public.

Moedas said: "I think that one of the things that has failed in the current programme is exactly these explanations," using this as one rationale for the upcoming Horizon Europe plan to adopt targeted research "missions"; one of which is set to be focused on cancer.

Meanwhile, at an event to launch the European Clinical Research Alliance on Infectious Diseases, the Research Commissioner said that some researchers had resisted the plan, because they think it will narrow spending to one topic only, for example Alzheimer's rather than Parkinson's.

Moedas's response has been: "No, I just want to have a couple of missions for people to engage with research in a way that they understand what we do."

As noted, cancer looks set to be one of five missions planned for the EU's research programme beginning in 2021, while a Council draft document defines the health category as: "Faster development and safer use of health innovations for European patients, and global health."

Meanwhile, in Slovakia, the government has approved a national oncology action plan that focuses on prevention through increased screening and better diagnostics.

The country, in which cancer is the second-highest cause of death, will also boost research and access to clinical trials.

MedTech, e-health and data protection

According to a recent survey, roughly the same number of notified bodies are gearing up to operate under the EU's incoming regulations for in vitro diagnostics (IVDs) as were operating under previous directives, although the scope of their jobs is a lot larger.

Some 85% of roughly 40,000 IVDs will have to get past a notified body for the first time from May of 2022.

Meanwhile, Ireland's health information agency (HIQA) has published a national standard for patient records for doctors to access in an emergency.

It cites the minimum patient information needed to help frontline healthcare professionals make decisions. The required information includes demographics, general health problems, medications and vaccinations.

And in Poland, the Deputy Health Minister **Janusz Cieszyński** has announced that a whopping 97% of the country's 14,500 pharmacies are now connected to the government's e-health platform and ready to start electronic prescriptions. The other 3% have a deadline of 31 December, this year, to fall into line.

Last month, meanwhile, in respect of the General Data Protection Regulation, EMA chief **Guido Rasi** said that the medical research sector needs clarity "immediately" on two points. These are secondary use of data, and who would be responsible if someone was able to identify data that was rendered anonymous in good faith.

Rasi said: "This lack of clarity is generating a lot of concerns in the investor [sphere], mostly outside the EU."

"Of course the GDPR has a lot of positive potential, but this, in the domain of research, can really be a stumbling block," he



romania2019.eu

Romanian Presidency of the Council of the European Union

added. In response, **Giovanni Buttarelli**, the European data protection supervisor, indicated that he “appreciates that EMA is paying full attention to the data protection implications of a modern medical research”.

However, he wanted to “respectfully disagree with (Rasi) by thinking in a more positive way about the above mentioned intersection”.

In Denmark, Copenhagen has said that the threat of health data being hacked is “very high,” so the ministries of health and the elderly are joining forces with Danish regions and municipalities to bring about a strategy to prevent attacks and respond to them quickly, when they do happen.

Training staff in using digital health systems and recognising phishing emails is a key element.

New year, new policies

At the start of 2019, several EU Member States clearly resolved to help their citizens get more healthy.

Germany is looking for healthier eating among its citizenry via an agreement with the food industry for voluntary cuts in sugar, salt and fat. The World Health Organization, however, has had experts out-and-about telling German media that taxing junk food is a better approach.

Public Health England, meanwhile, warned that UK children will have already gone over the maximum recommended sugar intake for an 18-year-old by the age of ten. On another note, Public Health England is also upping the promotion of e-cigarettes (or vapes) over traditional cigarettes, arguing that the former are 95% less harmful.

Not to be left behind, France has made smoking cessation aids pretty-much cost-free for users. The country has scrapped the €150 annual limit for nicotine-replacement patches, gums and lozenges.

And in a great leap, Estonia and Finland have officially become the first two Member States to share prescription data in both directions. Finland is currently working on a similar arrangement with Sweden.

7th annual presidency conference

EAPM will hold its 7th Presidency Conference in Brussels on 8-9 April. The event, entitled “*Forward as one: Healthcare innovation and the need for policymaker engagement*”, will this year be held in association with the Romanian Presidency of the European Union, which runs until the end of June.

The gathering comes on the back of the organisation’s second annual Congress, held in Milan in November 2018.

This year’s Alliance conference is slightly different from most of its previous large-scale events, in that the 2019 edition will take place during the run-up to the European Parliament elections in May and the new Commission entering the Berlaymont further down the line.

Key topics to be discussed will include personalised medicine and the innovation agenda, technology developments, hematology with respect to personalised treatment, and the regulatory framework surrounding pharmaceuticals and diagnostics.

Also up for discussion will be personalised prevention plus the impact of Brexit, and a session on the Million European Genome Alliance, known as MEGA, and its broader applications.

Summer School 2019

EAPM has already announced the dates, venue and key topics for its fourth annual Summer School for healthcare professionals, of HCPs.

Following in the wake of successful events in Cascais in Portugal, the Romanian capital of Bucharest, and Warsaw in Poland (plus a Winter School in Milan), this year’s edition will take place at the KU Leuven Faculty of Medicine, in Belgium, from 19-22 June.

Once again, the school will come under the umbrella of ‘TEACH’, which stands for Training and Education for Advanced Clinicians and HCPs, and the goal is to bring young, front-line professionals up-to-speed with fast-moving developments in the field of personalised medicine.

Aimed at age-range 28-40, TEACH holds to the thesis that, if



personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high-quality healthcare, then clearly it must be made available to many more citizens than is currently the case.

This year's over-arching subjects will be genomics and profiling. Where genomics in health stands today - and its incredible potential through Next Generation Sequencing (or NGS) and more - will be a key focus, backed up by discussions on key challenges to progression, and differing perspectives in this crucial and swiftly moving area.

Included in the topics currently under discussion by EAPM stakeholders is a look at what regulatory framework is best to support innovation in genomics.

In the news

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

[Are the Brits really aware of looming healthcare issues?](#)

[Key messages to modernise and optimise healthcare](#)

[Three heads are better than one: How the EU Presidency 'Trio' works](#)

[Digital transformation of health services in a modern Europe](#)

[Healthcare research: Moving the debate forward...](#)

[Stalled HTA needs to move up a gear](#)

[Update: Europe set for vital polls in May](#)

[Lack of information having an impact on cross-border healthcare](#)



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About EAPM

The European Alliance for Personalised Medicine (EAPM), launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

As the European discussion on personalised medicine gathers pace. EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

The mix of EAPM members 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. EAPM is funded by its members.

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