



# European Alliance for Personalised Medicine

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## Commission cash injection for healthcare

Welcome to our June newsletter. Health across the EU looks set to benefit from a €413 million injection as a result of the recent new budget proposal, with the Commission claiming this will lead to better integration of the so-called three Ps - promotion, prevention and protection.

EAPM will, of course, seek to add a fourth P - personalised.

As part of the 'health strand', as well as improving the treatment of rare diseases, orphan drugs and preparedness for pandemics, the proposal on EU-wide HTA will also get funding, should it be approved by Member States (see below).

Health areas under the Digital Europe and Horizon Europe (research) will be boosted, says the Commission, which will publish detailed proposals in June.

In general, the health strand looks set to ensure a higher level of health protection, reduce inequalities and address the challenges identified in the latest European Semester, which include sustainability and cost-effectiveness down the line. Twelve Member States received recommendations in the area of health.

For the full recommendations, click [here](#)

On health in general, many current issues have been key items that EAPM communicated during its 2018 Presidency Conference.

The following items will be a focus for the Alliance in conjunction with our partners going forward:

- Improving crisis preparedness and response against cross-border health threats
- Strengthening health systems (digital transformation, EU health information, support to national reforms)
- Supporting EU health legislation (medicines, HTA, tobacco, cross-border care)
- Supporting integrated work (European Reference Networks, implementation of best practices for health promotion and disease prevention)

Health-related resources will be part of the budget of several priority areas: social protection, research and innovation, the digitisation of society, cohesion and global responsibility.

### In the pipeline for 2018

- **6 June and 11 July: HTA roundtables, European Parliament, Brussels**
- **19-22 June: Third TEACH Summer School for healthcare professionals, Warsaw**
- **26-28 November: Second Annual EAPM Congress, Milan**

Health policies will get EU funding through various mechanisms, mainly:

- European Social Fund Plus (ESF+)
- Digital Europe Programme
- European Regional Development Fund (ERDF)
- InvestEU Fund
- Horizon Europe (EU research programme)
- Emergency Aid Rescue (rescEU)

### HTA and patent extensions

The European Parliament's draft report on plans to amend the directive on health technology assessment (HTA) will be the topic of a key Alliance meeting on 6 June.

The Brussels seat of Parliament will host the meeting being held to scrutinise the report distributed by rapporteur Soledad Cabezon Ruiz, MEP, and EAPM is already generally in support of its contents.

One day later (7 June) Parliament's lead committee on the issue (Environment, Public Health and Food Safety) will meet to consider the draft.

The draft is available [here](#)

Meanwhile, another key area to see EAPM's focus with the EU institutions is the recently mooted Supplementary Protection



Certificates (SPCs) which seek to extend patent protection for medicinal products.

The proposal targets intellectual property rules with the goal of helping EU pharmaceutical companies to tap into fast-growing global markets, the Commission says.

It adds that to improve the current system and remove a major competitive disadvantage of EU manufacturers, it proposes a targeted amendment: the 'export manufacturing waiver' to SPCs.

These extend patent protection for medicinal products requiring lengthy testing and clinical trials before gaining regulatory marketing approval. Read more, [here](#)

The Commission's HTA proposal, meanwhile, aims to introduce joint clinical assessment of health technologies at EU level, although this has met with some opposition from certain Member States who traditionally guard their individual competence in healthcare.

On top of this, a parliamentary committee in Ireland says it wants the Commission to include some in vitro diagnostics within the proposal. The country's joint health committee points out that such technologies are growing in importance and wants more medtech rather than less.

Despite some criticisms noted above, the Parliament's draft praises the Commission's proposal as 'timely' saying it represents high-added value. Parliament also feels it represents a further step towards closer EU integration in the health arena.

Parliament states in its draft that any policies regulating health and healthcare provision must have the aim of guaranteeing access to medicines for patients. Yet there is a great deal of concern regarding the reality of the situation.

It argues that Europe needs more and better clinical evidence, to determine the efficacy and therapeutic advantage of medicines.

Until now, Member States have made decisions on efficacy and

value on an individual basis, but the Commission and now Parliament believes that joint clinical assessment is the way forward. They base this partly on a need to avoid duplication across Member States, caused by a lack of clinical evidence across the EU and sub-optimal communication.

Other areas need improvement, the draft says, such as clinical evidence in respect of medical devices.

Meanwhile, Parliament feels that the proposal may bring about more collaboration in fields such as personalised medicine.

It adds that new ways must be found to deliver more of these personalised medicines, especially in the case of rare diseases and smaller groups, areas that EAPM firmly supports.

A new joint clinical assessment system across the continent will certainly have a part to play, as the Commission and Parliament clearly believe, and the trick is finding the very best way to do this and persuading the EU's individual countries to buy into the idea.

EAPM notes several meetings on the topics under the following timetable:

- Meeting to discuss the draft report - 6 June, European Parliament
- Deadline for amendments - 13 June at 11:00
- Consideration of amendments - 9/10 July
- Further meeting, European Parliament, 11 July
- Vote in ENVI (+mandate) - 10 or 13 September or mandate in October
- Plenary - October

#### **GDPR now in force**

Since 25 May we've all been bombarded with emails asking us to confirm our subscriptions and so on - EAPM has circulated one



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itself - as the General Data Protection Regulation (GDPR) entered into force on that day.

The Alliance had plenty of involvement on the topic in the run up to its implementation and will now continue its work on the Million European Genomes Alliance (MEGA) project, historically recently signed off by 15 Member States acting as a coalition of the willing.

EAPM's focus in this area will be developing the governance framework with partners and the Member States that signed the Declaration, which you can read [here](#)

The Alliance put forward MEGA in a bid to ramp-up the capacity of the Member States involved to implement personalised and genomic medicine, while gathering a cohort of at least one million genomes in the next few years.

But we will need infrastructure and more to do this, which will involve a coordination body. EAPM will turn its attention to helping to ensure that this happens, sooner rather than later.

### **Innovative networks**

EAPM has made considerable efforts over time to ensure that innovative networks are integrated into national healthcare systems.

Cristian Busoi, MEP, a long-time Alliance champion (who will be speaking at the HTA meeting on 6 June) recently asked a Parliamentary question on the subject of European Reference Networks (ERNs).

These are virtual networks engaging healthcare providers across Europe in order to facilitate discussion on complex or rare diseases and conditions that require special treatment, knowledge and resources, and that provide patients suffering from rare diseases with treatments offered by Europe's leading experts that are often unavailable in the patient's region or country.

Busoi asked the Commission how it views the efficient integration of ERNs within Member States' legal frameworks, including their national plans for rare diseases.

Health and food safety commissioner Vytenis Andriukaitis said

in response that their integration is one of the most important challenges faced by ERNs.

He added that the Commission strongly supports efforts to identify relevant actions to speed up this process.

Key to going forward, he highlighted strategic issues as:

- Establishing rules for the referral of patients to the ERNs, having first defined patient pathways in the national healthcare systems
- Agreeing on the form of support to be provided by the Member States to the Coordinators and the ERN members
- Facilitating costs reimbursement in case of patient mobility triggered by ERN advice

There are all issues that the Alliance will be following up through the SMART initiative, which stands for Smaller Member states And Regions Together.

### **Bulgaria Council Conclusions**

The Bulgarian-based EU Council Conclusions are due very soon, just before the country's first Presidency ends at the end of the month.

But already certain draft versions are circulating and EAPM has its hand on the tiller in an effort to guide the conclusions in the ideal direction in the arena of European healthcare.

One draft conclusion, on the European Open Science Cloud, or EOSC, was backed by EU ministers at the end of May.

EOSC is geared towards the better sharing of research data (a key goal of EAPM's MEGA, in essence) and, although presented under the Bulgarian Presidency, the Conclusions form the result of more than two years of negotiations. The aim is to get the data-sharing cloud operational by 2020.

Setting up a structure for governance is now key and, on 11 June, scientific and policy experts will meet in Brussels to discuss rules for participating in the cloud.

They will also draft EU-wide principles for data that has



been dubbed 'FAIR' (which stands for findable, accessible, interoperable and reusable). A follow-up meeting in November will aim to approve the governance structure.

This is all to be commended. However, EAPM was recently critical of a draft version of the conclusions, saying they lacked "clear and effective interrelations" among the different bodies that collect and control data.

Compared to other major economies, Europe suffers from a growth deficit which, together with the experience of uneven progress, fuels social disenchantment and political divisions across the continent.

At the heart of Europe's slow growth lies its innovation deficit. Europe does not capitalise enough on the knowledge it has and produces. Although not life-changing, the Conclusions, and their adoption, is a step in the right direction in order to bring much-needed focus to ways that can support innovation.

On we go...

### ***Third Summer School set for Warsaw***

EAPM's third annual Summer Summer School will be held in partnership with the Polish Alliance for Personalised Medicine and will take place in Warsaw from 19-22 June. The title of this year's edition is *New Horizons in Personalised Medicine*.

There is a great need for constant education in clinical implementation of personalised medicine, and this third international Summer School will give participants a unique opportunity to have discussions with, and learn from, leading experts (from Poland and beyond) in medical oncology,

gastroenterology, cardiology, radiation oncology and radiology, as well as in clinical and translational research, and more.

Once again, the school will be entitled '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.

Once again, the faculty has been chosen from medical academic, clinical, communication and research specialists and will cover, among many other topics, challenges and multi-dimensional implications in respect of personalised medicine.

Formats will include roundtables, keynote speeches, plus detailed discussions on personalised medicine and its different perspectives.

Also, sessions will feature subjects such as the basics of molecular biology in clinical practice, personalised medicine in combination with immunotherapy, colorectal cancer therapy and haemato-oncology among others.

Take a look at the agenda, [here](#)

### ***November Congress heads to Milan***

The second annual EAPM-run Congress will take place in Milan from 26-28 November, and we hope to see you all there.

Meanwhile, the report from last year's Congress in Belfast is available [here](#)

More than 1000 Life Sciences thought leaders are expected to converge on the Congress and, as it did last year in Belfast, the





event will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange. Learn more, [here](#)

EAPM is currently finalising the names for all of the Congress tracks with our sponsors, and this should be updated by the middle of this month.

As ever, the Alliance's focus is bringing innovation into healthcare systems while keeping the person in personalised healthcare.

We believe that the EU is well-placed to find the right mechanisms and balances to do this with some its laws and governance structures already heading that way.

Meanwhile, democratic principles are embedded in Member States and underpin systems that offer frameworks for collaboration, cooperation and coordination.

We are attempting to extend this through the MEGA initiative already mentioned in this newsletter, while working hard to ensure that the bloc has the right legislation and governance systems in place going forward.

#### ***In the news***

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

[#EAPM: Call for Bulgaria to be bolder on innovation in Council Conclusions](#)

[#EAPM: New #HTA draft report up for debate by health care experts on 6 June](#)



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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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