European Alliance for Personalised Medicine

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Starting gun fired in run up to EU elections

Welcome to our September newsletter. It may seem like 'early doors' but the 2019 European Parliament elections are less than a year away, now, and a new Commission will also be put in place at the start of 2020.

We're all in for a busy time, not least because of Brexit, as well as the ongoing debate on HTA and EAPM's focus on embedding innovation into the EU's healthcare systems.

Integrating innovation has always been a priority for the Alliance, its members and stakeholders. But there is a need to bring legislators fully on board at all levels across Europe and get them up-to-speed with new developments.

So while taking into account the aforementioned European Parliamentary elections, it is important to engage law- and policy-makers, both old and new, in a bid to push the agenda.

Innovation is key to health and wealth in the current EU-28 (and will be even more important after the UK leaves).

Early dialogue between technology developers, regulatory, health technology assessment and, where relevant, pricing bodies will promote innovation and quicker access to medicines at affordable prices, to the benefit of patients.

Unfortunately, there are far too few forums that allow this necessary inter-stakeholder dialogue, with the result that the people who need the fastest results most - namely the patients - end up losing out.

EAPM will continue to play its part in bridging that gap, with a continuing strategy aimed at highlighting innovations already taking place, as well as the need for incentives to bring about more.

Great deal on Congress

EAPM's upcoming 2nd Annual Congress (Milan, November) is the subject of a special offer: The first 350 non-industry registrants will benefit from complimentary passes to the event, available to quick-off-the-mark applicants.

The scheme is up-and-running here. and you can read more about the Congress elsewhere in this edition of the newsletter.

HTA as it stands

EAPM will also be playing its part in the ongoing debate on the Commission plans to further integrate HTA across the bloc, albeit amid controversy over the Executive's suggested mandatory elements, and objections from France and Germany among other Member States.

In the pipeline:

- **26 September: HTA meeting, Brussels**
- **19-23 Octoctober: ESMO Congress. EAPM Engagement**
- **6 November: HTA meeting, Brussels**
- **26-28 November: Second Annual EAPM Congress, Milan**

The Commission says that the proposal is aimed at improving the functioning of the internal market by harmonising the Member States' rules on carrying out clinical assessments for health technologies at national level, but several countries argue that it is stepping outside its competence under the treaties.

EAPM has been engaging with individual countries, the Commission and Members of the European Parliament in these areas, including holding meetings in Strasburg and Brussels.

Indeed, the Alliance will be hosting two roundtable meetings going forward on the topic - on 26 September and 6 November. The latter will see a focus on engagement with Member States.

The first meeting aims to provide a forum for MEPs within the healthcare community to discuss the amendments and for the Members to receive feedback from experts.

The overall goal of the roundtable is to give MEPs an understanding of the pros and cons of the current amendments and possible compromises seen from different stakeholders' groups.

Ahead of this, the European Parliament has been busy examining options and proposing detailed changes to the Commission proposal (see next item).

Back to work for institutions

An informal meeting on the HTA proposals mentioned above

was the first key gathering in the last week of August as the EU slowly made its way back from the summer break. A European Parliament vote is due on 13 September on the back of the Environment, Public Health and Food Safety (ENVI) committee's proposals for amendments, and the topic has apparently been discussed often over the last weeks, despite holidays.

Leading the way, rapporteur Soledad Cabezón Ruiz has flagged up a debate over the inclusion of medical devices in the Commission's proposals and also discussions regarding voting rules on adopting assessments.

The Alliance's key issues are to ensure that the new proposals allow Member States to strengthen cooperation in HTA and to ensure a better functioning of the internal market in respect of health technologies.

EAPM will be following events closely, so welcome back from your break and do expect regular updates. Not least as we will be working hard with MEPs to ensure that any eventual compromises address EAPM stakeholder priority areas.

Placating Paris

Meanwhile, the European Commission has tried to reassure the parliament in Paris that Member States will keep control over the pricing of pharmaceuticals and their reimbursement policies under its HTA proposal.

Writing to the French National Assembly, the EU Executive explained that countries would remain free to add what it called "context-specific information" to EU-wide joint clinical assessments.

The Commission added that assessments would be performed by individual Member States, rather than by the Commission itself, and reiterated its view that EU-level assessments should be mandatory in order to increase their quality.

The debate continues…

Ex-Belgium health insurance boss speaks out

Ri De Ridder (pictured above), who had been the director general of the Belgian National Institute for Health and Disability Insurance for a dozen years, has criticised the way medicines are developed and paid for by Western governments, just months after leaving his post.

Now president of international health charity Doctors of the World, De Ridder told *Le Soir* newspaper at the end of August that there is a need to "delink research and development, which should be handled by the public sector, from production and marketing".

He said that there is a lot of public investment in research and development but that intellectual property of the back of such R&D becomes private.

"We need the audacity to organise things differently. Health is a public good," the former health-payer chief said.

He added that there was nothing rational about how pharmaceutical companies set their prices and the fragmentation of the market means that countries are 'prisoners' of the drugs companies, and paying 'foolish' amounts of money.

Despite praising Belgium, the Netherlands, Luxembourg, Austria and Ireland (Beneluxa) for banding to gather to negotiate prices, the likelihood is that this won't change the model, he feels.

For her part, Belgium's health minister Maggie De Block, speaking through a spokesperson, said that she "is looking for solutions within the Belgian and European market economy. A government that takes on tasks that belong to the private sector, regardless of feasibility, is…a recipe of the past and therefore undesirable".

Given that the public puts health high on its list of priorities, the price of medicine is likely to be a crucial issue for the EU elections. This also holds true when it comes to ensuring faster diagnosis of harmful diseases and better access to patients at an earlier stage.

Meanwhile, Annika Strandhäll, who is Sweden's Minister of Social Affairs, revealed recently that government healthcare spending weighed in at more than 13 billion Swedish krona (€1.2 billion) this year.

Strandhäll said the government has made healthcare a priority over tax cuts and, to that end, has invested in staff and delivering more timely access for patients.

New drugs and therapy rules

In essentially its first week back at work, the European Commission has given final approval to two CAR-T cell therapies. This means that Novartis' Kymriah and Gilead's Yescarata are the first treatments of their kind to be made available in Europe.

This comes on the back of a recommendation from the European Medicines Agency (EMA) earlier in the summer.

The newly approved - and most likely hugely expensive - treatments can help to engineer a patient's own cells to fight certain blood cancers. They will initially only be available for children (although they been approved for adults), but that appears to be an issue of current production capacity.

Reportedly Novartis is looking at throwing money at facilities in Switzerland to ramp up production of its medicine.

In the meantime, long-time EAPM supporter Cristian-Silviu Buşoi MEP, alongside three Parliamentary colleagues, asked Commissioner Vitenis Andriukaitis why the Executive and EMA plan on advanced therapeutic medicinal products does not foresee changes to the present legal framework.

This is in the light of a 2014 report by the Commission that said that "too burdensome requirements could have detrimental consequences" when it comes to creating new treatments.

Commissioner Andriukaitis (pictured above) rejected the need for new rules, saying that a 2007 regulation already offers a "clear and specific framework" for dealing with such examples of personalised medicines.

He did concede, though, that applying existing rules "can be optimised'.

EAPM will be keeping a watchful eye on any developments in this area.

Meanwhile, the Commission has asked for comments in respect of guidelines on good clinical practice in clinical trials of advanced therapy medicinal products (such as the blood cancer drugs mentioned above). The Executive believes that such treatments have great potential and has asked for responses by 31 October.

Research chief says 'too early to set moonshot goals'

In respect of the Commission's post-2020 research funding proposal, which included the idea of health-specific 'moonshot missions' gaining special funding, Research Commissioner Carlos Moedas has said it's too soon to set goals for the programme that will run after 2022.

There is now a fear that the funding won't actually be made available, although the Parliament and Council want a deal done while passing the broader Horizon Europe package, the Commission's new research framework.

EAPM believes it is vital that healthcare is placed high up on the agenda, now and going forward, and will be engaging with lead rapporteurs in the European Parliament, namely MEPs Christian Ehler and Cristian-Silviu Busoi.

AI to treat cancer tumours

Researchers in France have come up with an algorithm to analyse changes that help to predict how a patient with a cancer tumour will respond to immunotherapy treatment.

The breakthrough is based on imaging technology, and will be an issue to be discussed out our Milan Congress in November and EAPM's Working Group on Translational Research going forward.

And in Hungary, a soon-to-be launched programme will aim to screen 2.4 million citizens for colon and rectal cancer over the next two years.

Colon cancer kills around 5,000 people each year in the

Member State and reports say that the EU will provide some €7.7 million to pay for the screening of around 300,000, with the currently unknown balance paid for by Budapest.

EAPM's members, associates and stakeholders will be well aware of the work that the Alliance has done to promote and push for lung-cancer screening programmes across the EU.

Working group and request on medical devices

The health ministry in Italy has set up its own technical working group to look at the main issues concerning laws on pharmaceuticals and medical devices. Those involved in the working group include medicine regulator AIFA, and the ministries of economic development, economy and finance.

For its part EAPM has regularly called for more dialogue at ministerial levels, especially concerning regions, and co-ordination at national levels as part of its ongoing SMART Outreach programme.

In terms of the impact of regulatory issues, a US-based medical device maker, Cook Medical, has asked for the transition agreement between the UK and EU to be extended from 2020 to 2025.

Britain's National Health Service is said to import some £5 billion worth of medical devices each year, and Cook Medical is calling for realistic timelines to apply in the In-Vitro Diagnostic and Medical Device Regulations.

EAPM will monitor this issue closely, primarily via its Regulatory Affairs Working Group. The topics will be up for discussion during our November Congress.

Patient-centric not pharma-centric

As the pharmaceutical industry works on the EU and UK to minimise the impact of Brexit, a new report states that companies' interests must mirror patients' concerns.

The report, by Portland Global Policy Communications, surveyed a combined total of around 275 MEPs and British MPs on the topic of the pharmaceutical industry and Brexit talks.

Although not a huge number was surveyed, very few elected Members (average around 15%) felt that the Brexit negotiations should give priority to pharmaceutical companies. In contrast, 56% felt that patients should be the top priority.

Countless EAPM meetings, plus discussions at Congress and conferences, have hilighted the key need to keep the person in personalised healthcare, as well as promoting earlier diagnosis and giving the right treatment to the right patient at the right time.

Vestager challenges markets

The Commission's competition chief Margrethe Vestager (pictured above) is attempting to push the envelope in respect of expectations on delivery by EU markets.

The commissioner recently blocked a couple of telecoms merger deals on the basis that "consumers needed the competition, both to keep prices down, and to spur companies to invest".

She did, however, pass a merger between chemical companies Dow and Dupont last year but was clear that innovation for safer and better products in the future is a priority.

The argument about whether lower prices, high quality and innovation can actually go hand-in-hand is hardly new, but the Danish commissioner said in Copenhagen recently that "competition helps push pharmaceutical companies to keep innovating new and effective drugs, and competition helps ensure that when our healthcare sectors purchase medicines they have competitive prices".

The counter-argument is, of course, that lower prices can discourage investment, while more actual investment ups the cost of running a business, leading to higher prices.

Verstager, in her Copenhagen speech, did acknowledge that "pharmaceutical companies do a huge amount of expensive research and innovation".

"They do a lot of tests at high cost."

EAPM believes that what is lacking, certainly in healthcare, is a system of incentives to make it worthwhile for pharmaceutical companies to invest heavily in new products.

And Vestager added that "the reward is the right to sell the drug exclusively over a certain period in time". But there is on-going confusion about how more innovation - and the cost of it - will actually lead to lower prices and increased competition.

Again this all ties in with EAPM's stated goal of making sure that innovation benefits healthcare systems and ultimately patients. Expect discussion at Congress in Milan.

MEGA and Big Data

EAPM has always pushed for transparency and the greater sharing of data, as evidenced by its MEGA project (Million European Genomes Alliance), which is now off-the-ground and will see continued involvement by the Alliance.

To recap, in April, at the European Commission's Digital Day 2018, 16 countries signed a Joint Declaration to collaborate on a groundbreaking one-million genomes project.

In front of high-level stakeholders in the fields of digital technology and telecommunication, representatives of Member States co-signed the Declaration indicating political support for linking existing and future genomic databanks.

This will work on a voluntary basis with the goal of making a cohort of one million sequenced genomes accessible in the EU by 2022.

EAPM originally floated the idea under the banner of MEGA and, with the leadership of DG CONNECT, the dream is set to become reality.

Watch this space…

Congress and the Italian Job

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

We are delighted to be working in partnership with the Regional Council of Lombardy for the event.

The report from last year's Congress in Belfast is available here and the Milan edition will seek to match last year's successful event in the Northern Ireland capital.

However, this year there will be one important difference: To reflect the multi-stakeholder and inclusive nature of EAPM, the Alliance has decided to launch a special registration offer.

The first 350 non-industry registrants will benefit from complimentary passes to the Milan event, available to quick-off-the-mark applicants. The scheme is up-and-running here.

At the Congress, more than 1000 Life Sciences thought leaders are expected to convene and, as it did last year in Northern Ireland, the event will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange. Learn more, here

This second annual Congress will pull together leading experts in the arena drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives.

The event comes under the title '*Forward as One: Integrating Innovation into Europe's Healthcare Systems*', and will provide the ideal space to allow for a meeting of minds and expertise and represent a vital opportunity for top-level discussion and the formulation of real action plans.

The Congress will amount to an ideal 'one-stop shop' with the aim of bringing innovation into the EU's healthcare systems.

Over three days, attendees will be able to select from more than 60 breakout sessions (or 'Tracks') in key sector-related areas including:

- Access and Early Diagnosis Track
- Diabetes Track
- Diagnostics and Medical Devices Track
- Education Winter School Track
- Genomics/MEGA Track
- Hospital Track
- Lung Cancer Screening Track
- Men's Health Track
- Patient Track
- Rare Diseases Track
- Regional Track

- SMEs Track
- Translational Research Track

A note on Lombardy

The Lombardy region represents 16,4% of Italy's population (about 10 million), produces 21% of national GDP, is host to more than 800,000 companies (99% of which are SMEs) and is responsible for exports in excess of 100 billion euro.

Lombardy is also home to 13 public and private universities, 18 institutes for treatment and research, 12 national research council institutes plus 29 public hospitals and assistance centres, so has plenty to offer those working in the arena of healthcare.

In the news

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

Ongoing #HTA debate sees upcoming key meeting in European Parliament

Collaboration key to getting the ball in the health-care net

EAPM Congress – Forward as One: Integrating Innovation Into Europe's Health-Care Systems

Facing up to the economics of genomics in the personalised medicine era

Debate on SPCs sees Commission and Pharma at odds

Impact of medicines on the environment to be tackled by Commission

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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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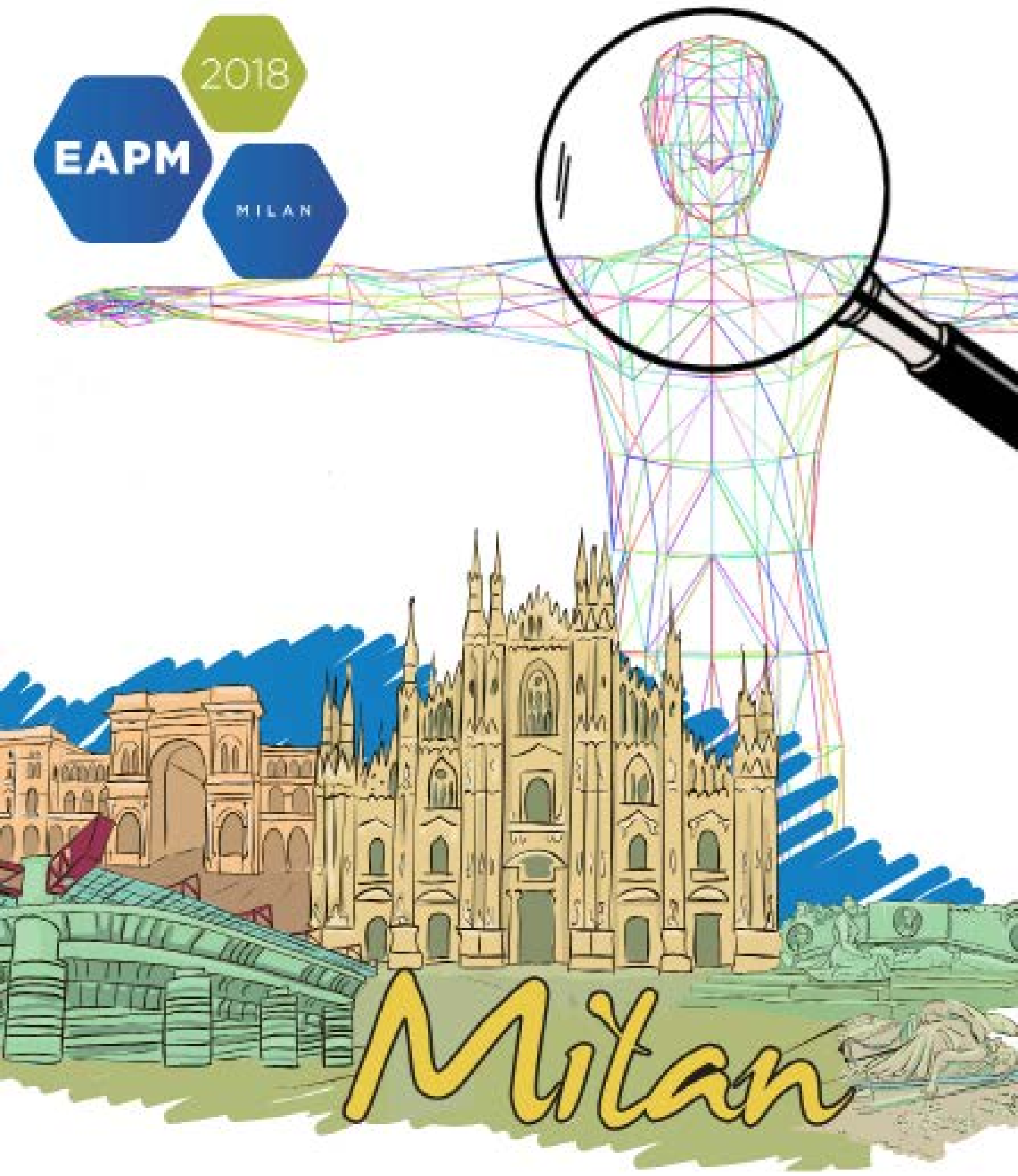

2nd European Alliance for Personalised Medicine Congress

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