European Alliance for Personalised Medicine

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Austrian Presidency outlines healthcare plans

Welcome to EAPM's August newsletter. Europe has been in the grip of a heatwave, and things will certainly be hotting up for the Alliance and its members and partners after the summer holidays, with plenty going on before our second Congress set for November in Milan (26-28). More of that later.

Here's a recap of recent events, meanwhile…

Austrian Presidency of the EU

The Austrian Presidency has been in place for a month now and, early in July, there was an exchange between Beate Hartinger-Klein, the Austrian Minister for Labour, Social Affairs, Health and Consumer Protection, and the European Parliament's Environment, Public Health and Food Safety (ENVI) committee.

The Minister spoke about the Presidency's health, health technology assessment (HTA) and digitalisation of healthcare programmes (as well as other topics) to be worked on between now and the end of December when the Presidency finishes.

The motto of the Presidency, is "a Europe that protects" and, of course, it is in the forefront as we run up to Brexit at the end of March and the Parliamentary elections in May.

There is great deal of legislation needed to be put to bed before the elections and it was pointed out that the Committee disagreed with the health programme being part of the ESF+ (the broadened European Social Fund). The concern is that it will be lost during such a big programme in the run-up to the EU-wide vote.

To put it in perspective, the Commission has proposed €413 million for health programmes in the next budget, a relatively small part of the €100 billion dedicated to the ESF+ plans.

More broadly, the Austrian Minister pointed out that the Presidency can only achieve progress if it is based on the unity of the EU and Member States, while emphasising that one key priority will be EU competitiveness in the context of digitalisation specifically (this will be a topic during the informal health ministers meeting on 10-11 September in Vienna).

This will take into account the conclusions of the preceding Bulgarian Presidency which finished at the end of June and the Commission communication on a stronger digital contribution to healthcare.

Minister Hartinger-Klein outlined that a key priority is investment in digital health infrastructure. Another priority is regulatory and healthcare policy challenges in medicine authorisation (this will see discussions with EU healthcare ministers and the EMA).

In the pipeline:

• 26 September: HTA meeting, European Parliament, Brussels

• 26-28 November: Second Annual EAPM Congress, Milan

Also, from a legislative point of view, the Presidency says it will focus on HTA in Council discussions - a hot topic in the EU at the moment and one also being debated regularly in EAPM meetings.

The Commission plans have been controversial and Austria says it has listened to Member States (both for and against) and will aim to draft a new version of the proposal.

Other health-related topics set to come under the Presidency microscope will be tobacco control, vaccinations, food law and drinking water.

Contrary to the ENVI committee concerns mentioned above, the Minister was positive about the health action plan being part of ESF+ as it strengthens the EU's Social Pillar.

Yet there is a need to acknowledge the importance of health in all policies at the EU level, including environmental standards, as they protect health generally and quality of life.

During the meeting, MEP Peter Liese flagged-up that European citizens regularly died because of antimicrobial resistance. He called this "a grave issue", while his fellow MEP Miriam Dalli called on the Austrian Presidency to be ambitious in order to ensure EU-wide cooperation to avoid diseases preventable by vaccinations.

Ms Dalli also asked what kind of commitment the Minister could make to the Parliament in respect of pharmaceuticals and HTA.

Soledad Cabezón-Ruiz wanted the Minister to note that Parliament is concerned about what has been said in the Council on HTA and had been working on bringing positions together.

She gave the opinion that Member States should have a bigger role in HTA and suggested, up to the moment, the current voluntary approach is sub-optimal.

Cristian-Silviu Buşoi said that the health programme needs to be made more efficient.

The Minister, replying to MEP Ruiz, emphasised that there is increasing cooperation in HTA across the EU but that the Presidency is aware of the need for discussions to achieve maximum progress in the limited time available.

HTA - the background and EAPM's role

Back in June, big guns France and Germany published their views on the European Commission's controversial proposals for mandatory joint clinical assessment (JCA) on HTA. The latter were widely rejected by the larger Member States at a meeting of EU health ministers in Brussels, earlier that month.

TThe two countries rejected the mandatory option, although said that, in principle, they support a more profound, voluntary cooperation at EU level in the area of HTA.

They added that "well-organised and high-quality cooperation can assist Member States in preparing their healthcare decisions, in particular regarding pricing and reimbursement".

But they said that conditions must be right and retain the room for manoeuvre at national level, in implementing healthcare decisions, as well as in pricing and reimbursement.

"It should only be required that EU-level clinical assessments be taken into consideration at national level, instead of having them obligatorily applied," the two countries said.

EAPM is engaging with individual countries, the Commission and Members of the European Parliament on an ongoing basis on the issues arising.

Indeed, the Alliance hosted a meeting at the Strasbourg seat of Parliament last month, involving MEPs and key stakeholders on the subject of cooperation in HTA, to address the potential impact of the various options.

EAPM will hold a further meeting on HTA in the Brussels Parliament on 26 September (12.30-14.00). This will come under the title of '*Aligning the priorities between the healthcare community and the European Parliament: Where we are now and the necessary next steps for a regulatory framework for HTA*'.

The meeting is designed to provide a forum for MEPs within the healthcare community to discuss the compromise amendments and for members to receive feedback from experts.

In particular, the roundtable wishes to support the goals of the HTA proposal which include enabling Member States to strengthen their cooperation on HTA in a sustainable manner, and ensure a better functioning of the internal market of health technologies.

The overall goal is to give MEPs an understanding of the pros and cons of the current amendments and compromise amendments seen from different stakeholder groups.

Since the original proposal from the EU Executive it has been made clear that the Commission believes that, although Member States have been cooperating on HTA for two decades, now is the time to step up commitments in this area.

There is a need, the Commission, Parliament and EAPM believe, to bring experts together to create scientific reports that are inclusive and more general, in respect of HTA in EU healthcare systems.

As alluded to above, EAPM is generally in support of the Commission proposal, which leans in the direction of the mandatory use of joint clinical assessment of health technologies at EU level (albeit after a three-year transition period).

Any changes to the HTA system are aimed towards higher quality assessments using independent experts and geared towards firm, evidence-based decisions.

The Commission, the European Parliament and EAPM all believe that joint clinical assessment would avoid duplication across EU countries, caused by a lack of clinical evidence and less-than-optimal communication.

HTAs are currently fragmented with different systems, different procedures and different requirements regarding the type of clinical evidence. This has generally been bad news for patients in Europe and certainly doesn't help cash-strapped healthcare systems who are casting around for 'value'.

In lower-resourced and often smaller EU Member States there is often an issue in that they are unable to set up their own adequate HTA systems, and these countries would benefit from better EU-wide cooperation, allowing them to use European-wide HTA and adopt results locally.

The debate will continue, but speedy access to safe treatments and new drugs for patients must be the priority.

Reimbursement is a further issue, and the World Health Organization recently published a lengthy report, which you can find here

Orphan drugs latest

The European Commission has said that it will be looking for formal feedback in order to assess views on its evaluation of how the orphan drugs regulation is functioning. It will do this in the autumn with the health sector being consulted as well as the general public.

In the context of orphan drugs two main areas exist in which optimal or even satisfactory treatments are often not available, namely in the sphere of rare diseases and in children.

Estimates suggest that there are 5000 to 8000 distinct rare diseases in the EU alone, but medicines are often not produced as returns for pharmaceutical companies would, by definition, be small, there is a higher complexity, and incentives and reimbursement levels are not adequate, although the EU says it has taken measures to rectify this, given that it is acknowledged that here is not enough research going on in these areas.

More on drug pricing...

With the BENELUXA group (made up of Belgium, the Netherlands, Luxembourg, Austrian and Ireland) having finally done their first successful deal on joint drug pricing negotiations - with Biogen for the spinal muscular atrophy drug Spinraza - the similarly aimed Valetta group is yet to have the same success.

The Valetta grouping is made up of ten mostly southern European countries and recently bemoaned a lack of "institutional safeguarding and legal shielding of the process," via Greek Health Minister Andreas Xanthos.

It seems that the members need to come up with a framework that will make the results of the negotiations legally binding. This will offer pharmaceutical companies incentives to engage in negotiations, said the health minister.

He added that: "This motivation is easy and quick access to very large markets without waiting for each country to make its own assessment and negotiation."

A downside, Minister Xanthous added, is that there is currently no agreement to halt parallel procedure "at national level for medicines evaluated and negotiated by Valletta".

E-health and MEGA

An analysis by Mercom Capital Group suggests that investment in digital health projects using venture capital cash is on the rise generally, but Europe is largely missing out. The analysis showed that none of the top ten beneficiaries of funding are in the EU.

On the plus side, the European Medicines Agency (EMA) has said that its scheme to allow general citizens, researchers and academics to direct access to thousands of pages of clinical reports from pharmaceutical firms has been a great success.

EAPM has always pushed for transparency and the greater sharing of data, as evidenced by its MEGA project (Million European Genomes Alliance).

In April, at the European Commission's Digital Day 2018, 15 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.

Research in the EU

MEP and EAPM backer Cristian-Silviu Bușoi, a doctor and member of the Parliament ENVI committee, says that the institution wants more money for research and development to be allocated than currently proposed by the Commission.

Busoi wrote, citing a Eurobarometer survey: "Seventy percent of Europeans want the Union to do more in the health sector." He added that the Commission should boost funding for health to 9.7 percent of the total research budget, up from the 8.18 percent currently proposed for the post-2020 research programme.

Meanwhile MEP Dan Nica, who is rapporteur on the Horizon Europe proposal, wants more money to be spent on health research.

Aside from the MEPs' comments, research ministers meeting in Vienna said they were concerned about missions set to be funded under Horizon Europe finding "the concept still incomplete".

The ministers also discussed how to spend a proposed €94 billion over seven years on science, with the current Austrian Presidency looking to reach broad consensus on the allocation of the resources by the end of November.

Brexit back up

The UK is stepping up its contingency plans if the soon-to-leave Member State exits the EU in a no-deal scenario.

It will be asking industry to start 'stockpiling' in areas such as medicines, vaccines, medical devices, clinical consumables and blood products.

Medical devices

EAPM has always backed bringing innovation into the EU's healthcare systems, and this applies to the regulations on medical devices.

The rules came into force one year ago, but there is still a two-year transition period on the go (plus more time for in-vitro devices).

Recently, eight cross-party MEPs tabled a question including the following statement: "It is proving difficult to prepare all the necessary elements of the system and in particular to designate the necessary notified bodies on time."

And given Brexit, mentioned in the item above, the MEPs will also be asking the Commission whether certificates granted by notified bodies in Britain will still be valid in the EU once the UK leaves.

And speaking of notified bodies (who check the quality and safety of medical devices), during the next two years there will have to be a speeding up of the process of their re-approval by authorities in order to hit the deadline.

The word is that the Commission aims to complete 40 to 50 assessments this year, in advance of approving all relevant devices in the EU ahead of the end of the transition period.

Bulgarian Presidency Council Conclusions

The Council Conclusions from the Bulgarian Presidency were endorsed by all Member States in the European Council meeting of 28 June.

In our health sphere the relevant passages were as follows:

• Europe must further develop its high-quality research across the EU and turn it into new products, services and business models. We need a stronger, inclusive innovation ecosystem to foster breakthrough and market-creating innovation and

provide comprehensive support for businesses, including SMEs, with disruptive potential to successfully enter global markets.

• It is vital to deliver on the remaining legislative proposals concerning the Digital Single Market before the end of the current legislative cycle.

• To build a European data economy, further action is needed to improve the efficient use of data across the EU and foster trust through high data protection standards and full implementation and proportionate enforcement of the General Data Protection Regulation in respect of all economic actors doing business in our single market.

• High-quality data are essential for the development of Artificial Intelligence. The European Council invites the co-legislators to swiftly examine the latest data package. It invites the Commission to work with Member States on a coordinated plan on Artificial Intelligence, building on its recent communication.

• The European Council insists on improving businesses' access to financing, including by better coordinating EU and national research and innovation funding schemes and instruments, on providing a favourable regulatory environment that supports greater risk-taking, and on promoting digital skills as well as links between academia, industry and governments.

• Cooperation between research, innovation and education should be encouraged, including through the European Universities initiative.

• The European Council invites the Commission to launch a new pilot initiative on breakthrough innovation within the remaining period of Horizon 2020. A European Innovation Council will be set up under the next Multi-annual Financial Framework to identify and scale-up breakthrough and disruptive innovation.

Milan to host November Congress

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

It is with great pleasure that we can inform you that the Alliance will be working in partnership with the Regional Council of Lombardy for the Congress.

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.

Our cooperation with Lombardy perfectly reflects our SMART initiative, (Smaller Member states And Regions Together) which seeks to optimise how regions can support bringing innovation into Europe's healthcare systems.

In the news

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

Legal threat to parallel trade in medicines watered down by EU

EU heavyweights show Commission HTA proposal yellow car

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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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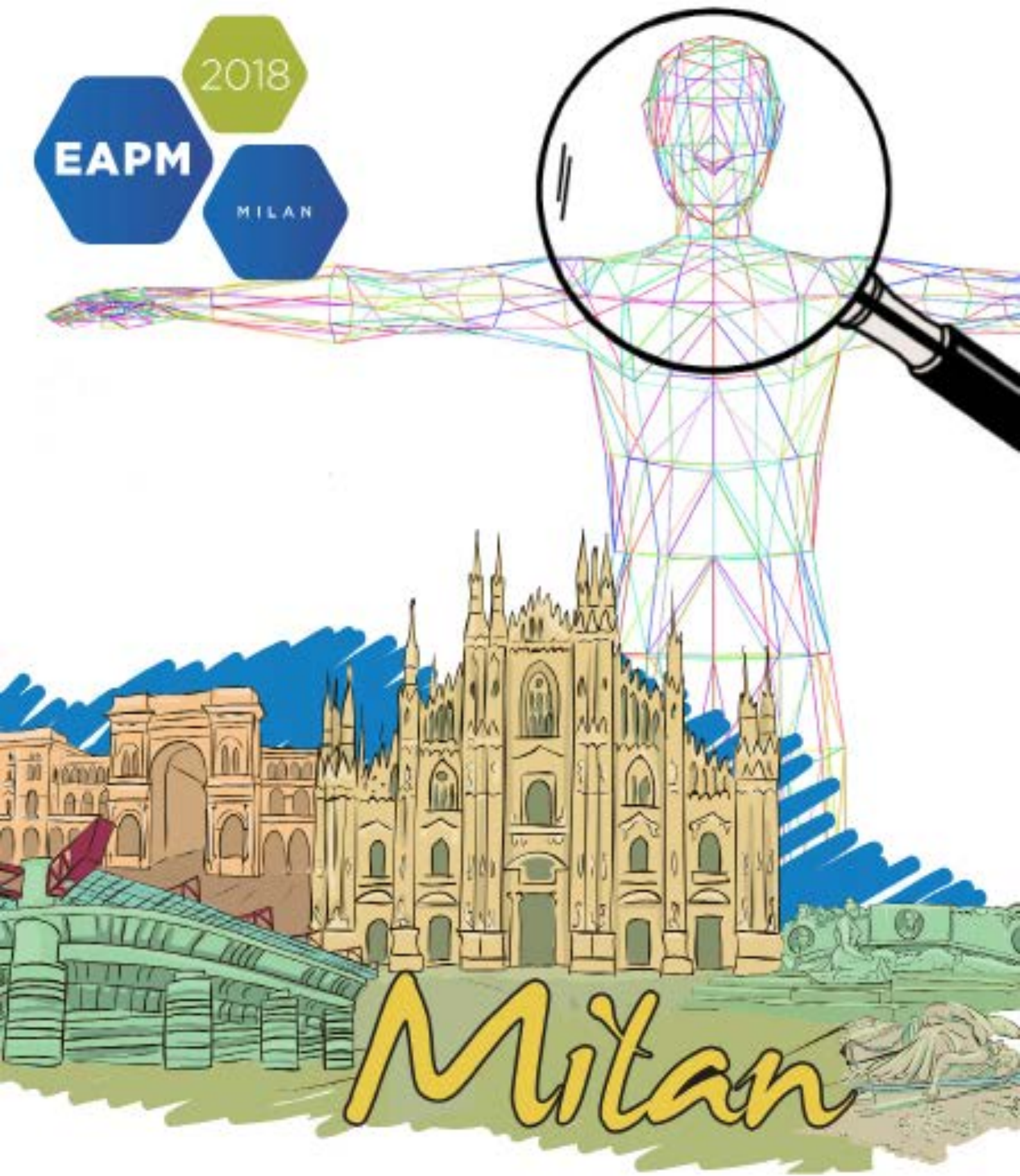

2nd European Alliance for Personalised Medicine Congress

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