



European Alliance for Personalised Medicine

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EAPM tracking all new developments

2015 started in very busy fashion for the Alliance – as outlined in our first newsletter, [here](#) - and March and beyond will be no different..

EAPM has taken note of new developments already this year, such as the landmark 23andMe ruling by the FDA in the US – see our article [here](#) – as well as relevant aspects of the European Commission's 2015 Work Plan.

The latter include cutting red tape and 'clearing the decks' by withdrawing or modifying some pending legislative proposals. Also highlighted are proposals on working to create a new boost for jobs, as well as a connected digital single market.

These could all have an impact on the health sector and its stakeholders in this legislature and further into the future.

March 2015

Coming up this month, on 16 March, is a Regulatory Taskforce meeting that will discuss issues related to the definition of companion diagnostics, the sharing of data for research purposes and clinical trials/MAPPs.

Now is a crucial time for data protection - being discussed at the Justice and Home Affairs Council meeting, with a particular onus on the health-related issues – as well as in-vitro diagnostics, which are also being discussed by the Council. The timing of the Alliance meeting is therefore particularly pertinent.

March will also see the launch of our Personalised Medicine Literacy Survey. European researchers have been at the forefront of major scientific discoveries in cancer. The challenge is how best to translate this expertise into personalised medicine approaches that improve outcomes and enhance well-being for European patients. Increased knowledge and understanding of personalised medicine and its potential among healthcare professionals is a key enabler for its future integration into European health systems.

March at a glance:

- 16 March - Regulatory Taskforce meeting to discuss issues related to the definition of companion diagnostics, the sharing of data for research purposes and clinical trials/MAPPs

- **Launch of stakeholder surveys on Personalised Medicine Literacy and Big Data.** The results garnered from this poll will be analysed and prepared for scientific publication and will inform the development of a personalised medicine education strategy. A second survey will concern Big Data.

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The Big Data survey will result in a short concept paper in order to raise interest and garner support for a personalised medicine domain. This falls within the scope of the PPP on Big Data, signed between the Big Data Value Association and the Commission.

In order to increase literacy, it is necessary first to determine the current levels of understanding and the potential knowledge gaps.

The survey questionnaire has been divided into 22 close-ended questions and will take stakeholders around 25 minutes to complete. It will remain completely anonymous. The second step in this process would be the evaluation of current levels of literacy via a quantitative structured series of questions which would be the subject of a voting poll.

The results garnered from this poll will be analysed and prepared for scientific publication and will inform the development of a personalised medicine education strategy.

A second survey will concern Big Data. The EC's Communication 'Towards a thriving data-driven economy' of July 2014 provides the example of personalised medicine as a domain able to support "lighthouse" data initiatives capable of improving competitiveness, quality of public

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June conference latest

The EAPM conference has been moved to 2-3 June in order to allow the participation of Luxembourg Health Minister. Luxembourg is investing in facilitating an environment for personalised medicine and will have it as one of its political priorities, as well as formulating Council Conclusions.

Of course, June will still see Latvia at the helm of the European Union, until it is followed by Luxembourg on 1 July. EAPM is working with both presidencies to help further the cause of personalised medicine and bring about the goal of delivering the right treatment to the right patient at the right time.

EAPM believes that health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries (such as Latvia and Luxembourg) and in the regions of the larger ones. We call this a SMART approach – Smaller Member states And Regions Together. This will be further developed at the conference.

The Alliance is of the view that if the presidencies, the European Parliament and the Commission work in harmony this will improve the quality of life for patients in every country in Europe.

The ongoing STEPs campaign

In line with EAPM's Specialised Treatment for Europe's Patients initiative (STEPS) we therefore call on the EU to commit to the following:

- **STEP 1:** To ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine
- **STEP 2:** To increasing R&D for personalised medicine, while also recognising its value

- **STEP 3:** To improving the education and training of health-care professionals

- **STEP 4:** To supporting new approaches to reimbursement and HTA, that are required for patient access to personalised medicine

- **STEP 5:** To increasing awareness and understanding of personalised medicine

About EAPM

The European Alliance for Personalised Medicine (EAPM), launched in March 2012, brings together European health-care 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 European Medicines Agency. EAPM is funded by its members.

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