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a. Major European research project on monitoring and evaluation of medicines concluded

On 19 and 20 February the European Medicines Agency (EMA) hosted a symposium to present the conclusions of the five-year project 'Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium' ([PROTECT](#)).

PROTECT is a public-private partnership of 34 European partners funded by the Innovative Medicines Initiative Joint Undertaking (IMI). Its aim has been to develop innovative methods to strengthen the monitoring and evaluation of the benefits and risks of medicines marketed in Europe.

The symposium brought together the results and key recommendations of PROTECT and discussed how the findings can be applied. In this sense, EMA will systematically scrutinise PROTECT's research outputs in order to identify priority results that are robust and which, if implemented, have the greatest potential to positively impact public health.

The methods developed by PROTECT are intended to strengthen the monitoring and evaluation of the benefit-risk of medicines marketed in Europe by:

- enhancing early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies);
- establishing a framework for pharmaco-epidemiology studies;
- examining new methods for data collection from consumers;
- exploring approaches to integrate benefit-risk methods into scientific assessment of medicines and the subsequent communication of these benefits and risks.

b. Horizon 2020: new projects to foster equity in research

New 13 ERA Chairs to foster excellence in Europe

[Thirteen](#) universities, technical institutes and private organisations in those parts of Europe that have not done as well as they could in research and innovation are to receive up to €2.5 million each in EU funding to boost their research capacity through the appointment of "ERA Chairs", the European Commission announced in February.

The funding, coming from the EU's research and innovation funding programme, Horizon 2020, will enable these institutions to attract top academics so that they can compete with centres of excellence elsewhere in the European Research Area (ERA). The aim is to bridge Europe's innovation divide by making sure that no one with potential is left behind.

New grants to help close the gap in research excellence across Europe

The EU announced new grants that will help bridge the research excellence gap between Member States and strengthen competitiveness and growth across Europe. This new instrument is called [Teaming](#). The grants that are awarded under this framework will help improve research performance and increase investment in countries with lower research excellence rankings.

With funding from Horizon 2020, 31 projects from such countries have now been selected to prepare operational plans for new Centres of Excellence by teaming up with high-calibre institutions from all over Europe.

c. The dispute over the future of the Chief Scientific Adviser (CSA) rumbles on

In reply to 3 different Parliamentary questions on the issue, [President Juncker](#) claims that he has not "abolished" the position of Chief Scientific Adviser (CSA), but the mandate was linked to the previous Commission President and so expired with the end of his term of office. He explained that he had asked Commissioner Moedas, in charge of Research, Science and Innovation, to present



options “on how better to institutionalise future scientific advice” to the Commission, “based on the experience made in all the Member States”.

The 3 questions reflect the different views of MEPs. Marc [Tarabella](#) (S&D/BE), welcomed the news and claimed the role had put too much power in the hands of an individual, ran counter to the collegiality of scientific expertise and the expression of minority views. The questions from [Neena Gill](#) (S&D/GB) and [Hans-Olaf Henkel](#) (ECR/DE) were more supportive of the position and Henkel blamed lobbying by Greenpeace and Corporate Europe Observatory (CEO) for the abolition of the post.

d. Consultation on the ex-post evaluation of the 7th Framework Programme

The European Commission has opened a consultation on the ex-post evaluation of the 7th Framework Programme (FP7). FP7 is the EU research programme predecessor of Horizon 2020. The Commission is seeking opinions about the functioning, achievements, and impacts of FP7 in order to feed the evaluation of the programme.

Especially sought are contributions from research and higher education institutions, business, policy makers, local public authorities, innovators, entrepreneurs and civil society organisations.

The deadline for submitting opinions is 22 May 2015. To participate and for more information, please click [here](#).

EU Public Health Policies

a. EMA establishes an EU taskforce on the identification of medicines

The European Medicines Agency (EMA) is [establishing](#) a task force for the implementation of international standards for the identification of medicinal products (IDMP) for human use in the European Union. The Agency is inviting interested

parties to express their will of becoming part of the task force.

These standards concern data formats and terminologies for the unique identification of medicines. They are expected to simplify the exchange of information between regulatory authorities across the world and to support them in the development of electronic health. In order to open a dialogue on the issue amongst different stakeholders, EMA has established an EU taskforce that will deliver in 2015 an EU strategy; a road-map; and an implementation guide.

The task force will include representatives from the EMA; the national competent authorities in EU Member States; the pharmaceutical industry as nominated by the EU pharmaceutical industry associations; software vendors, service providers and developers of medicinal product dictionaries or data bases; and other interested parties such as organisations with expertise in terminologies supporting the electronic exchange of information on medicines and substances.

b. Study on the links between lifestyle and the efficiency of Europe’s health systems

DG SANTE released in February the [report](#) ‘Comparative efficiency of health systems, corrected for selected lifestyle factors’. Selected lifestyle factors considered are smoking, overweight and alcohol consumption.

Although the report is clear on the impact of healthier lifestyle on life expectancy (it points at a potential 3 years of life increase), the text says that that it is difficult to determine how lifestyle impacts health spending when the overall wealth GDP per capita is taken into account.

The research covered 28 Member States, Iceland, and Norway. Individual level data were used to describe lifestyle across age and gender and to analyse its impact on health outcomes and health care use. Health outcomes and health spending were standardized for differences in lifestyle using a lifetable model.

The report's conclusions include:

- On average, more health spending is associated with better health. This effect is clearest for countries with lower levels of spending. However, it was not possible to distinguish between the impact of health spending and GDP from the data.
- There is a substantial variation in lifestyle habits between countries.
- A positive relationship between healthy lifestyles and health outcomes exists, in particular for smoking and BMI (body mass index).
- A slightly positive relationship between unhealthy lifestyle and health care use was found.
- If all countries had health behaviours at the same level and prevalence as the countries with the healthiest lifestyles, life expectancy would increase, with increments varying from 0.4 to 3.1 years.
- Healthier lifestyles would result in a more efficient health system. However, this overlooks the fact that improvements in lifestyle are themselves reached at a cost and take time. In practice, better lifestyle behaviour involves costs. However, the review also showed that cost-effective interventions to reduce unhealthy lifestyles do exist.
- The current cross-sectional results do not support the notion that smoking, BMI and alcohol use are important confounders when establishing the comparative efficiency of the health systems of countries in Europe.

c. TTIP: Leaked document contains wording for safeguard of public health systems

The BBC published on 26 February a [leaked draft](#) table containing what the EU wants to exclude from TTIP (Transatlantic Trade and Investment Partnership).

The document is called 'Trade in services and investment: schedule of specific commitments and reservations' and was produced before the latest round of negotiations in Brussels, which took place early February.

On health, the document states that the EU "reserves the right to adopt or maintain any measure with regard to the provision of all health services which receive public funding or State support in any form."

However, advocates for an explicit and total exclusion of health services from TTIP are concerned about the effects of the [Investor-State Dispute Settlement Mechanism](#) envisaged in TTIP, arguing that American investors in public health services that are privatised now or in the future will be able to use TTIP to sue the government if it tries to bring them back into public hands.

European Commission spokesman, Daniel Rosario, responded that "no existing free trade agreement would prevent any government from renationalising any public services" and that the countries "can keep public monopolies and regulate public services as they see fit." There is a [letter](#) from EU Commissioner for Trade, Cecilia Malmstrom, in the same sense.

d. The eHealth priorities of the Commission

Pēteris Zilgalvis, Head of the Unit Health and Wellbeing (European Commission), explained the eHealth priorities of the Commission in an [interview](#) with mHealth Global. He also outlined how the authorities and stakeholders will work together to determine the actions that need to be taken in regards to mHealth.

On the [results](#) of the consultation on mHealth, he stated that the Commission was going to discuss with stakeholders eventual actions in the areas of concern, such as trust, security evidence and the digital single market.

He added that the Commission will consider some of the suggestions of the responses to the consultation, such as the establishment of guidelines/code of conduct on mHealth, or even legislative proposals.



e. JA-CHRODIS – One year on

On 19 February, the EU Joint Action [CHRODIS](#) held its First General Assembly and its 2nd Stakeholder Forum one year after its launch.

An EU Joint Action (JA) is a programme set up by the Commission to facilitate collaboration between Member States in a particular area – in this case chronic diseases and healthy ageing. CHRODIS is the biggest JA to date, in terms of budget, but also regarding the number of partners. JAs are co-financed by the Commission (under the EU Health Programme) and by the relevant Member States authorities in the field.

Key-note speaker of the Forum (open to external stakeholders) was Prof. Raymond Vanholder on behalf of the European Chronic Disease Alliance (ECDA). He outlined the great individual, societal, and economical burden of chronic diseases, stating the need to invest much more in prevention (including research) and to tackle chronic diseases according to its reality: a net of different conditions interconnected to each other. In this sense, and aligning with CHRODIS' approach, Prof Vanholder emphasized the multimorbidity aspect and the need to adopt an integrated care approach to benefit the patient's outcome and improve use of health resources.

ECDA's keynote speech was followed by the contribution of Commission, DG SANTE, Ms Eibhilin Manning, who presented the Commission's work in the [European Innovation Partnership on Active and Healthy Ageing](#) and its intertwining with CHRODIS.

The next round of interventions was for the CHRODIS Work Packages (WP) leaders to explain their progress:

WP4 deals with the (open) online platform for exchange of good practices in chronic disease policies. It will have three sections: 1) the Digital Library (containing all the information, without filters); 2) the Clearinghouse (containing only evaluated best practices); and 3) the Helpdesk (offering a more customised service)

WP5 will compile best practices on health promotion; they seem to be in the very early stage

of development. An interesting contribution came from the audience: someone pointed out to the need to look into the psychological determinants for (not) adopting healthy lifestyles.

WP6 is charged with the best practices on multimorbidity. They are operating in a four- step approach: 1) identifying the targets (patients using a lot of healthcare resources), 2) reviewing the current practices on multimorbidity, 3) selecting the valuable practices, 4) in order to introduce them in the teaching programmes. There will be a CHRODIS monographic issue covering the multimorbidity care situation in the 8 countries of study. The leader of the WP took the opportunity to call for experts in integrated/multimorbidity care in order to fulfil the tasks of the WP adequately.

f. SCENIHR: opinion on BPA in medical devices

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has published its [final opinion](#) on "The safety of the use of bisphenol A (BPA) in medical devices".

Concerning exposure via the oral route (dental products), the SCENIHR has concluded that the risk is negligible. However, it notes that risk for adverse effects may exist, when the BPA is directly available for systemic exposure (non-oral), especially for neonates in intensive care units, for infants undergoing prolonged medical procedures and for dialysis patients.

Despite this, the Committee warns that the possibility to replace BPA in these products should be considered against their efficiency in the treatment, as well as the toxicological profile of the alternative materials, when available.

g. Healthy lifestyle conference kicks off in Riga

The Latvian [Presidency](#) of the Council of the European Union has organised a major [conference](#) in Riga on healthy lifestyles, focusing on nutrition and physical activity for children and young people. The conference provided an opportunity to

assess the current progress on EU and national efforts on nutrition and physical activity and to discuss the way forward in reducing childhood obesity and promoting healthy lifestyles. The conference included presentations by Dr. Gauden Galea of the World Health Organisation's Regional Office for Europe ([WHO Europe](#)) ([link](#)), Philippe Roux of the European Commission's Directorate-General for Health and Food Safety ([link](#)), Prof. Tim Lobstein of the World Obesity Federation ([link](#)) and Stephan Loerke of the World Federation of Advertisers ([link](#)). The discussions focused in particular on the promotion of healthy lifestyles in the school environment, including school meals, health education and health literacy, physical activity, and modern technologies for children and young people to promote healthy eating habits.

Environmental Health

a. Commission keeps commitment on Air Quality Package

On February 24, the European Parliament's Committee on the Environment, Public Health and Food Safety hosted Commissioner Karmenu Vella for an exchange of views to discuss the environmental objectives of the Commission for 2015. After facing the Greens explaining the withdrawal of the circular economy package, the Environment Commissioner Vella confirmed that the same won't occur with the air quality [proposal](#). The file remains on the table and the Commission will put forward a revised position in the course of negotiations to reflect synergies with energy and climate policy. These proposals will be focused on reducing burdens without compromising the original goals. He said it was important to move the discussion to a political level, and maintain the strong level of ambition. The Commission is committed to a speedy and satisfactory solution on the national emissions directive. Regarding the other half of the package, the medium combustion plants directive, the Commission hopes for a positive outcome that delivers on the overall emission targets, and will do everything to facilitate the agreement.

Annexes

a. Parliamentary questions

Questions answered in February:

Question E-010626-14:

[Radioprotection training recognition](#)

Question E-010574-14:

[Medical sharps directive](#)

Question E-010238/2014:

[Elimination of the position of Chief Scientific Adviser](#)

Question E-010097/2014:

[Commission initiatives for the EU pharmaceutical sector](#)

Question E-010738/2014:

[Promoting medical innovations](#)

Question E-010201/2014:

[Prizes for successful research/demand](#)

Question E-010279/2014:

[Potential barriers to the development of academic research in Regulation \(EU\) No 536/2014 on clinical trials on medicinal products for human use](#)

Question E-009450/2014:

[Availability of medicines in EU hospitals](#)

Question E-010648/2014:

[Pollution of waste water with medical residues](#)

Question E-009775/2014:

[Medicine shortages problem in Europe](#)

Question E-010741/2014:

[Quality of training and mobility of doctors within the European Union](#)

Question E-009364/2014:

[Electronic health records](#)

Question E-010848/2014:

[eHealth, wearable medical devices and cybercrime](#)

Question E- 011250/2014:

[Equivalence of professions and qualifications in the EU](#)

Question E- 011124/2014:

[Obesity in Europe](#)

Question E- 010559/2014:

[High-risk medical devices](#)

Question E- 010417/2014:

[The quality of hospital equipment in Greece](#)

Questions tabled in February:

Question E- 002000/2015:

[Online safety logo to protect citizens from falsified medicines](#)

Question E- 001256/2015:

[European programmes supporting research in the field of paediatric medicine](#)

Question E- 000927/2015:

[EU position paper on medical devices in TTIP negotiations](#)

Question E- 002273/2015:

[Social attitudes towards vaccination, and vaccine uptake](#)

Question E- 002582/2015:

[Bisphenol A, studies and precautions](#)

Question O-000017/2015:

[Criteria for identifying endocrine-disrupting chemicals](#)

Question E-002376/2015:

[Suppressed report on the dangers of endocrine disruptors](#)

Question E- 002220/2015:

[Restrictions on access to medicines that can save lives](#)

Question E- 001860/2015:

[Healthy lifestyle promotion](#)

Question E- -001725/2015:

[Respiratory diseases](#)

b. EU events tracker

- [3 March, MEPs hosted EFPIA event The business of research: Enabling policies for the medicines of tomorrow, Brussels](#)
- [3 March, Adapting EU health policy to an evolving Europe, with participation from Commissioner Vytenis Andriukaitis, Brussels](#)
- [3 March, The European Brain Council holds an event "Criteria for success: The future of collaborative brain research, Brussels](#)
- [9 March, The European Summit on Innovation for Active and Healthy Ageing, Brussels](#)
- [10 March, The European Association of Research Managers and Administrators holds a two-day event on Horizon 2020 and its impact on research and innovation, Brussels](#)
- [18 March, webinar by EUBusiness on Clinical trials for Horizon 2020](#)
- [19 March, Multi-stakeholder public debate on the roadmap for sustainable healthcare, Brussels](#)