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**NOTE**

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From: Presidency  
To: Council

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Subject: **Employment, Social Policy, Health and Consumer Affairs Council**  
meeting on 7 December 2015  
Conferences organized by the Presidency in the field of public health  
– *Information from the Presidency*  
(Any Other Business item)

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Delegations will find attached an information note from the Presidency on the above mentioned subject.

**Information on the conferences and high-level meetings in the field of public health,  
pharmaceuticals and foodstuffs organized by the Luxembourg Presidency**

**1. High-Level Conference: “Making Access to Personalised Medicine a Reality for Patients”, Luxembourg, 8 July 2015**

Just a few years ago, personalised medicine was not well known or only partially understood by decision makers in the field of public health. This is gradually changing, since many initiatives and organisations have put the concept on the agenda, such as this conference – co-funded by the European Commission -, to which a wide variety of representatives from Member States, the Commission, stakeholders and experts participated.

At present, personalised medicine is not properly integrated into clinical practice, even if its benefits have been increasingly recognised in the last decade, particularly in the field of cancer treatment. The discussions showed that there is a need for a patient-centred long term EU agenda dedicated to the citizens' access to personalised medicine. Participants acknowledged the many obstacles that exist in relation to its integration into daily clinical practice; in some Member States however, good practices show that these obstacles can be overcome.

All sessions shared a common conclusion: a patient-centered approach, ensuring the involvement of the latter through a cross-sectoral approach is a key element, just as cooperation and enhanced collaboration between disciplines, between Member States and at EU level. Policy makers must show greater determination to go ahead and explore innovative options based on cross-cutting approaches.

The conference was structured around a number of sessions that covered the following areas:

- The voice of the patients - A patient oriented healthcare
- Addressing known obstacles to integrating Personalised Medicine into health systems
- Best practices: Learning and Sharing
- The value of Personalised Medicine for Public Health, its impact on EU Health Policy and its global dimension.

The first session focused on four pillars: the involvement and empowerment of the patient through good communication and the concept of shared decision-making; data exchange; the concept of "informed consent" and patient-centered care. The second session addressed the adjustment of HTA methods; flexible ways of placing medicines on the market ("adaptive pathways"); the training of health professionals; the crucial role of biobanks and the identification of innovative payer models. The third session revolved around the exchange of best practices from France, Belgium, the United Kingdom and Luxembourg. In the last session, participants stressed the need for an inter-sectoral approach involving the preclinical and clinical work, academic research, patients and industry. At the level of decision making, cooperation must take place at several levels within the Member States by supporting projects of the European Union, in cooperation with the European Medicines Agency, the Commission and international actors.

Based on the results of the conference, the Presidency presented Council conclusions on personalised medicine that for adoption by the Health Council on 7 December 2015.

## **2. Heads of Medicines Agencies (HMA) Meeting, Luxembourg, 7-9 July 2015**

During the 81th HMA Meeting, the HMA Multi-Annual Work Plan to implement the EU Medicines Agencies Network Strategy has been discussed in view of its adoption. This Strategy will be valid until 2020, forming the basis for a better coordinated approach and strengthened collaboration within the network of EU medicines agencies.

The Heads of Medicines Agencies adopted the EU Telematics Strategy, inviting industry stakeholders to participate in the follow-up activities of the EU Telematics strategy and recognizing the significant impact of EU Telematics on the pharmaceutical industry. Furthermore, the EU Network Training Center (NTC) Strategy and the Joint EU-NT Communication Strategy have been endorsed.

Additionally, the HMA Task Force on Time Tables has been discussed. Its aim is to optimize the time tables for applications in the Centralized Procedure, the Mutual Recognition Procedure and the Decentralised Procedure, both human and veterinary. Further dialogue with industry will be used to encourage the development of principles for a joint best practice between NCAs and industry.

With regard to European Cooperation in Health Technology Assessment (HTA), the crucial issue of business predictability by reimbursement has been raised. Participants suggested establishing a sustainable mechanism of joint work and of a reuse of the HTA structure by 2019. The European Commission Services expect to obtain specific outputs from the cooperation between regulatory and HTA bodies.

During the HMA Veterinary Meeting, experts from national competent authorities and industry discussed how to improve the availability of veterinary vaccines against the background of a recently published report from the joint HMA/EMA workshop and outlined the potential for the HMA/EMA action plan involving industry and other experts. The aim is to develop proposals to enhance availability of veterinary vaccines whilst maintaining the current high level of protection of animal and public health and the environment.

3. **High-Level event “30 years of EU action against cancer”, Luxembourg, 15 September 2015**

To mark the 30<sup>th</sup> anniversary of the first action on cancer, this high level event, jointly organized between the Commission and the Luxembourg Presidency, in parallel to a meeting of the Expert Group on Cancer Control, offered the possibility to take stock of the results achieved and to reflect on the long-term vision of EU action on cancer control.

The participants included the 60 members of the expert group and around 60 invited participants drawn from the European Parliament, (MEPs against cancer), patient groups, health professionals, and high level personalities.

The event was structured around three panels, the first of which was dedicated to the historic background of EU Action on cancer and long term perspective, allowing participants to look back on EU action on cancer from the perspective of the first "Europe Against Cancer programme" and on its "success stories". The second panel entitled "Continuity from 1985 to 2015" put a focus on national cancer plans and on the European Code against Cancer as well as the dissemination throughout Europe of best national practices or legislation. During the last panel, participants draw conclusions for the years to come on the basis of the finding that, while the institutional setup remains similar to the one 30 years ago, the landscape of stakeholders has indeed undergone some change. Non-governmental organisations have increased not only in number but also in terms of the range of their interest and activities which complement governmental and intergovernmental initiatives.

In light of the principles of the first days of the European action in the field of cancer, there is a potential to increase the engagement at European level and to build new partnerships, explore new methods in a policy area which directly affects and improves the quality of life for citizens and essentially addresses the theme of a "social Europe", in fighting against major inequalities.

#### **4. Informal Meeting of Ministers of Health, Luxembourg, 24-25 September**

The Informal Meeting of Ministers of Health started with discussions on the priorities of future cooperation between Member States and at EU level in order to improve care policies and practices in the field of dementia with a view to reduce the socio-economic burden of this disease. A specific focus was placed on timely diagnosis and post-diagnostic support to make secondary prevention most effective. The results of the debate informed the Council conclusions "Supporting people living with dementia: improving care policies and practices", adopted by Ministers of Health on 7 December 2015.

During the working lunch, Ministers held a debate on the possible ways forward in order to ensure that consumers are most efficiently informed on the presence of industrially produced trans fatty acids (TFA) in their food and the measures to be taken at EU level in order to reduce their presence in our daily diet, thus giving Ministers the opportunity to provide a strategic input to the Commission's report "regarding trans fats in foods and in the overall diet of the Union population", due since 13 December 2014 and finally published on 3 December 2015<sup>1</sup>.

Against the background of an increasing number of country specific recommendations in the field of health addressed to Member States by the Commission, the Presidency offered Member States the occasion to exchange on the added value of a more comprehensive assessment of healthcare performance in the frame of the European Semester, not merely limited to the fiscal dimension, but also addressing quality, access and effectiveness.

During the second day, Ministers exchanged on the role of action at EU and national level in order to ensure appropriate access to refugees and migrants to healthcare services adapted to their needs and on the necessity to integrate considerations on refugees and migrants' health matters into relevant national and EU policies.

The Informal Meeting closed on the exchange of Ministers on how to ensure a more efficient application of the Directive on cross-border health care services, two years after its transposition deadline. Ministers agreed that further action is requested in order to enhance the provision of information to citizens on their rights under the Directive as well as in the field of cooperation between Member States, notably in border regions.

##### **5. Meeting of the Heads of European Food Safety Agencies (HoA) – Luxembourg, 29 September 2015**

The Luxembourg competent authority, assisted by the Secretariat for Heads of Agencies hosted by the Netherlands, organized the second of the bi-annual collaboration and networking meeting between competent authorities for food safety.

The meeting gave the opportunity to exchange views and share best practices in order to verify compliance with food law and to improve harmonisation of legislation enforcement in presence of the Commission and the European Food Safety Agency (EFSA).

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<sup>1</sup> COM82015)619 final

The participants stressed the importance of continued common efforts in insuring that food safety measures continue to be able to respond to new challenges and of the ongoing review of related legislation.

Different cooperation issues were discussed. The group highlighted the measures to be taken against campylobacter as a food safety risk. It was also agreed to consider the use of industry laboratory data in governmental food safety control risk assessment. Furthermore common strategy for the use of social media for communication of food safety issues will be established in working groups of agency experts.

#### **6. Conference “Food Contact Materials: Working together for Safety and Innovation in Europe”, Luxembourg, 30 September 2015**

The conference brought together different representatives working in the food contact materials area, representatives from the European Commission, the Council of Europe, the European Food Safety Authority (EFSA), Member States experts and from the industry.

The main focus was laid on the aspects of safety an innovation. How can the safety of food contact materials be ensured in order to protect consumers? What challenges is this area faced with? What advantages does innovation bring to both consumers and industry? Consumer expectations, risk analysis and the challenges of official controls at different levels were also key discussion elements. The event also offered a constructive meeting opportunity for the EFSA focal point network.

#### **7. Conference on European Reference Networks “From Planning to Implementation”, Lisbon, 8-9 October 2015**

Co-organised with the Commission and hosted by the Portuguese Ministry of Health, the conference aimed to discuss and raise awareness on the state of the art concerning the organisation of highly specialised networks and centers of health expertise across the EU.

The conference brought together highly specialised healthcare providers, experts, national authorities, decision-makers, patient and professional organisations and offered them the possibility to exchange information and expertise on establishing and assessing European Reference Networks. It furthermore allowed participants to look into the next steps of the deployment process, in preparation for the call for European Reference Networks in 2016.

Participants widely agreed on the added value of the Networks in helping to improve access to both diagnosis and treatment, resulting in high quality and cost-effective health care for patients with a medical condition requiring a specific concentration of resources or expertise, particularly where such resources and expertise are rare.

**8. Ministerial Conference “Lessons learned from the Ebola outbreak in West Africa – how to improve preparedness and response in the EU for future outbreaks”,  
Mondorf-les-Bains, 12-14 October 2015**

The objective of this conference, which was co-organised by the Luxembourg Presidency and the European Commission, was to identify and examine the lessons learned from the epidemic and consequently to strengthen safety within the European Union, by improving the preparedness and response capacity of Member States in case of future public health emergencies similar to the Ebola outbreak.

The conference provided a multi-sectoral exchange, involving both the political and the expert level. It brought together ministers of health from various Member States, the Director of the WHO, the two commissioners in charge of Ebola V. Andriukaitis and C. Stylianides, and many stakeholders actively involved in the fight against Ebola.

The most important lesson identified at the conference was that inter-sectoral cooperation is most crucial to achieve and maintain preparedness and response capacities. In addition, the Ebola virus has led to new methods of cooperation and collaboration in the field of crisis management. The conference can be seen as a significant moment in the international discussion and showed that global governance on health topics should be revisited and transposed into efficient operational actions.

During the conference, four parallel workshops were organized.



The first one focused on the issues that mainly contributed to the Ebola epidemic having evolved into a complex emergency. Coordination, risk assessment procedures and inter-sectoral cooperation were identified as crucial to enhanced preparedness. The second workshop focused on best practices and lessons learned in the field of preclinical and clinical management, as well as the response to Ebola in the field of research. The third workshop revolved around risk communication procedures in case of emergency situations. The role of the Health Security Committee Communicators network was considered crucial, it should be active and operational to respond adequately to any future crises. The last workshop invited participants to consider the state of preparedness and response planning in the context of global health security. Countries showing verifiable preparedness and response mechanisms were indeed able to face the challenges and repatriate infected European health professionals. Similarly, the development of innovative mechanisms to manage clinical cases is vital. Good practices, such as training of health professionals and their implementation, should be developed in times of non-crisis.

The first prize of the EU Health Award 2015 Ceremony, that was awarded during the conference, went to the Alliance for International Medical Action for the initiative “Emergency medical response to the Ebola Virus Disease”.

The outcomes of the conference led to Council Conclusions “Lessons learned for public health from the Ebola outbreak in West Africa – Health Security within the EU”, adopted by the Council of Health ministers on December 7<sup>th</sup> 2015.

#### **9. Joint Meeting of the EU Chief Medical Officers and Chief Nursing Officers (CMO-CNO), Luxembourg, 12-13 October 2015**

The meeting allowed to address several priorities of the Luxembourg Presidency, such as Personalised Medicine and Dementia. The CMO representatives discussed the role of healthcare professionals and new communication modes in relation to the challenges linked to vaccination coverage.

Discussions also highlighted the need to continue the work on patient safety, notably via the exchange of best practice within the European Commission Expert Group on Patient Safety and Quality of Care. Participants also stressed the need to further develop cancer plans and to promote multidisciplinary approaches in addressing cancer.

The joint meeting furthermore recognised the importance of knowledge and skills of healthcare professionals in fostering technological innovation, health promotion and disease prevention. The creation of new roles for the nursing staff was highlighted just as the need to address the lack of adequate training of nursing students in the field of care for elderly patients suffering from dementia.

CMOs described the pathway that newly-arrived migrants have to follow when entering their country and the kind of healthcare assistance they are provided with. Representatives acknowledged that the current influx of migrants calls for their immediate attention.

#### **10. Annual Meeting of the Advisory Forum of EFSA, Luxembourg, 8-9 December 2015**

The annual meeting of the Advisory Forum of EFSA will be held in Luxembourg from 8 – 9 December 2015. A particular focus will be put on the EFSA Strategy 2020 as well as on the EU risk assessment agenda and forthcoming risk assessment activities.

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