

LUXEMBOURG PRESIDENCY HEALTH PRIORITIES: MEDICAL DEVICES, PERSONALISED MEDICINE, DEMENTIA, CROSS-BORDER CARE AND HEALTH SECURITY

By: Anne Calteux

Summary: Against the background of a Commission agenda dictated by the “less is more” principle, the health priorities of the upcoming Luxembourg European Union Presidency will focus on innovative and patient centred health care. These two objectives will guide the work on the revision of legislation in the field of medical devices and medical devices *in vitro*. They will also steer the reflections on how to facilitate patients’ access to Personalised Medicine, in accordance with the principle of universal and equal access to high quality health care. Patients will again be at the centre of discussions on innovative care models in the context of dementia, as well as on the implementation of the cross-border health care directive.

Keywords: *Medical Devices, Personalised Medicine, Dementia, European Presidency, Luxembourg*

Introduction

The setting of the upcoming Luxembourg European Union (EU) Presidency differs substantially from the context of its last Presidency back in 2005, exactly ten years ago. The decision making process has changed. The accession since 2004 of many new Member States has led to a fundamental renewal of the traditional relationship of strengths within the Council and the European Parliament takes its role as co-legislator more seriously than ever. Furthermore, with the Juncker Commission taking office

at a particularly challenging time for the EU, the agenda setting has undergone a change of direction. The willingness to make a new start and to address shortcomings in the field of jobs and growth has had a direct impact on the role and responsibilities of the different European Commissioners and has led to the definition of new priorities articulated around the principle of “less is more”.

In particular, the Commissioner in charge of Public Health and Food Safety, Vytenis Andriukaitis, will now contribute

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to initiatives steered and coordinated by the Vice-President for Jobs, Growth and Competitiveness; a “partnership” which may raise questions as to whether the objectives of public health policies systematically follow the same logic as the one underlying the portfolio of the Vice-President.

In the field of public health, the focus will be on the clearly delineated mandate of Commissioner Andriukaitis: the support to the EU’s capacity to respond to crisis situations in food safety and pandemics; the review of the decision making process in the field of GMOs; and the performance assessment of health systems, in line with the European semester.

At the beginning of the Presidency Trio in which Luxembourg is involved, along with Italy and Latvia, the priorities of Commissioner Andriukaitis were yet to be defined. This is no longer the case since their announcement to the ministers of health in April.² The health agenda will be defined around the three “Ps”: prevention, promotion and protection.

Presidency priorities

The upcoming Luxembourg Presidency will focus its priorities in the field of public health around the objective of enhancing the protection of citizens’ health while contributing to the sustainability of public health systems and to an innovative European Union. This objective will be addressed in various ways by topics which lie at the heart of societal debate, always putting patients at the centre of discussions.

Medical devices

Patients and their security, in particular, is one of the main aims of the revision of current legislation on *medical devices and medical devices in vitro*. The Council has failed to agree on a common position for this proposal since its presentation in 2012. Luxembourg will, on the basis of the excellent progress achieved during the Latvian Presidency, make all necessary efforts to enable the implementation of a solid regulatory framework, allowing quick access for European citizens to products of high quality and security without hampering the competitiveness

of the innovative European market. Negotiations will be brought to a new level once the trilogues* with the European Parliament will have been launched.

Personalised medicine

Another subject high on the political agenda of the Luxembourg Presidency is *Personalised Medicine*, a theme which has recently received much media attention. A High Level Conference will trigger discussions on how to make access to innovative medical interventions, tailored to the specific needs of individual patients, available to a larger number of patients, thus providing better treatment and preventing undesirable adverse reactions while fostering a more efficient and cost-effective healthcare system.²

Personalised Medicine starts with the patient. It features ambitious potential for improving the health of many patients and can help to ensure better outcomes for health system efficiency and transparency. Yet, its integration into clinical practice and daily care is proving difficult given the many barriers and challenges to targeted health care efforts. If personalised medicine is to be in line with the EU principle of universal and equal access to high quality health care, then clearly it must be made available to many more citizens than it is now. What is requested is a long-term approach to innovation to ensure the translation of new therapies from laboratories to patients. Recent initiatives in the UK and US, among other countries, have put this innovative method of diagnosing and treating patients in the spotlight while demonstrating that it is necessary to build frameworks that allow the delivery of the right treatment to the right patient at the right time, in accordance with the principle of equal and universal access to high quality health care.

Incorporating patients’ perspectives into the regulatory process will help address their unmet medical needs. Moreover, in times of budgetary constraints, facilitating better-targeted and more cost-efficient treatment—to a potential 500 million

patients in 28 EU Member States—is in line with the *Europe 2020* strategy and the aims of the Juncker Commission.

The High Level Conference is expected to contribute to the definition of a patient-centered strategy involving EU decision makers and regulators in the arena of public health, to enable the EU and Member States to contribute to integrating personalised medicine into clinical practice while enabling much-greater access for patients. The conference’s main findings will feed into Council Conclusions to be adopted by the 28 health ministers during the Council of Health Ministers in December 2015.

Dementia

Dementia will be another health priority of the Luxembourg Presidency. We know that the prevalence of dementia will rise. Dementia is more than a mere medical or social care issue. Dementia also concerns partners, relatives and friends and is a common challenge for our communities. A cross-sectorial and comprehensive view on the multifaceted challenges of dementia should guide further actions at national and at European level.

Contributing to healthy ageing in general should be a key policy goal. Besides the necessity to establish quality care for all people depending on care and especially dementia patients with their special needs, it is important to intervene at the earliest possible stage. This is the reason why during the Luxembourg Presidency, prevention—especially at primary and secondary level—as well as early diagnosis and post-diagnostic support will be more specifically addressed.

The discussions will focus on a comprehensive approach allowing not only adequate standards on timely diagnosis, but also multi-dimensional secondary dementia prevention programmes (post-diagnostic support) with advice on health related issues and additional counselling on social issues, general disease information, life-style related issues, family and financial matters, legal aspects and other related issues. Evaluation of these programmes will help us to also

* Trilogues are informal tripartite meetings attended by representatives of the European Parliament, the Council and the Commission.

enhance primary prevention measures and can serve as best practice examples for other EU Member States.

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Many EU countries are dealing with an ageing population, the increase of age-related diseases like dementia and the vulnerability of health care services. In order to achieve progress and make innovations possible and sustainable, it is necessary to collaborate in an international framework. Dementia will not only be a priority of the Luxembourg Presidency but it has also been addressed recently under the Italian Presidency and will be followed on by the Presidency of the Netherlands, starting 1st of January 2016 and hopefully thereafter.

Cross-border health care

During the Informal Council in September 2015, health ministers will take stock of the implementation of the cross-border health care Directive, two years after the transposition deadline. Although cross-border health care concerns only a minority of EU citizens, this milestone text has the potential to contribute in the long term to better access and better quality in health care for a large number of patients. The provisions on Member States' cooperation will be of particular relevance in this respect. The first progress report which will be presented by the European Commission during the next few months will be a key opportunity to assess whether the Directive has actually been of added value for patients and Member States, and to highlight its strengths but also potential barriers in implementation, and new rights compared to existing ones.

The Commission report is expected to focus on various aspects such as information on patient flows, the financial dimension of patient mobility, the implementation of the provisions on reimbursement and prior authorisation,

cooperation between neighbouring Member States, as well as the functioning of national contact points.

Health security

Finally, during the Luxembourg Presidency, the time will be ripe to evaluate how the Ebola crisis has been addressed. Luxembourg will be closely associated with the organisation by DG SANTE of a conference on “Ebola lessons learned”. After the recent commitments made by the World Health Organization (WHO) in relation to this issue, it is now up to the European actors to undertake the same exercise as in 2010 after the outbreak of the influenza A/H1N1 pandemic.

The conference will bring together many actors to ensure a cross-sectoral discussion on various themes, such as new strategies for treatment and prevention, including protection of health care workers, medical evacuation, diagnostic methods and vaccines, but also communication, inter-sectoral cooperation, preparedness activities and global health security. The reflections will take into account the work done by WHO in this field and their results will feed into the agenda of the December 2015 Council.

References

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