



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 4 December 2013

16572/13

SAN 463

NOTE

from: General Secretariat of the Council
to: Council

Subject: **Employment, Social Policy, Health and Consumer Affairs** Council meeting on
9 and 10 December 2013

Outcomes and Conferences of the Lithuania Presidency
- Information from the Presidency
(Any Other Business item)

Delegations will find in the Annex an information note on the above-mentioned subject.

Information on the conferences
organised within the framework of the Lithuanian Presidency

1. Informal meeting of Ministers for Health, Vilnius 8-9 July 2013

There were two plenary sessions on the first day of the meeting of health ministers and one session on 9 July. There was a working lunch on 8 July. The heads of delegations had an opportunity to exchange views on the sustainability and effectiveness of health systems, with a particular focus on social and economic areas, the best ways to prevent young people from starting smoking and the need for better promotion and protection of the mental health of older people. There was also a discussion on EU health policy after 2013 in the light of new challenges.

The outcomes of the meeting can be identified as follows:

- During the first plenary session the ministers pointed out that the discussion on the sustainability of health systems is timely, as demographic data shows that the population in Europe is ageing. More expenditure on health and more pressure on health systems are inevitable outcomes of the ageing of populations, and this is why smart reform is necessary. The economic crisis is an additional factor in reconsidering how health systems function and what they should look like in the long term.
- Innovative technologies are an essential part of a health system oriented towards a sustainable future, not only in terms of new machines and products but also in terms of organisational structure and management and models of funding and spending.
- In addition, health ministers recognised that coordinating actions with finance and economy ministers is the way to find effective solutions for funding, investing and reforming health systems. The health sector not only uses funds, it also generates economic benefits. Health spending should not be considered a cost but an investment.

- Strengthening patient involvement and empowerment and increasing health literacy and access to high-quality information are forward steps towards effective preventive programmes leading to a healthy life.
- It was agreed during the working lunch that the principles of the EU health strategy 2008-2013 are even more important in the light of new challenges and that these not only require close cooperation but also bring new opportunities for improving the health of Europeans.
- The main subject of the second plenary session was the mental health of older people. Getting older brings many stressors which may increase mental disorders, and which, together with economic difficulties, were reflected in the prevalence of depression, anxiety, increased alcohol consumption and suicidal behaviours; thus it is clear that the mental health of older people deserves more attention.
- According to many participants it is extremely important for both European society and the health workforce to be able to respond to the current and future mental health needs of older people, by providing an adequate level of health promotion, prevention, care and treatment.
- There is a need to provide opportunities for older people to stay active for longer in the workplace, community and family, because social isolation is a risk factor. If needed, effective treatment should be provided in both community and institutional settings.
- During the last plenary session the ministers urged that smoking, one of the most damaging habits for health, should be dealt with at EU as well as at Member State level. Despite the importance of consumer protection, products which are known to kill their users are available for sale and easily accessible. Substantial changes should be made to the regulation of tobacco product ingredients and emissions, labelling and packaging, and traceability and safety features. Furthermore, attention should be given to novel tobacco products, as new ones are constantly placed on the market.

- It was agreed that awareness-raising campaigns aimed at young people are an important tool for informing people about the consequences of using tobacco products. The advertising, promotion and marketing campaigns conducted by the tobacco industry influence adolescent smoking behaviour. It is evidenced in many Member States that tight restrictions on such promotional activities help to reduce the numbers of smokers.

2. Heads of Medicines Agencies (HMA) Meeting, Vilnius 10–11 September 2013

During the HMA meeting in Vilnius, the European Commission (EC) presented an update on developments, since the last HMA meeting in April 2013, in the ongoing Commission work covering the legal proposal on fees for pharmacovigilance (PV) activities. The EC proposed a joint action on PV, which would support Member States in exchanging experience and knowledge for organising and running their PV systems in the context of the new EU pharmacovigilance legislation.

The Commission has continued to work on the implementation of the Falsified Medicines directive. An update on the importing of active substances into the EU was presented. The Commission, together with the Active Pharmaceutical Ingredients (API) Task Force, monitors the implementation of the new rules. No reports of shortages of API or any other critical situations were received.

The Medicines and Healthcare Products Regulatory Agency (MHRA, UK) presented an overview of the current situation regarding the importing of active substances into the EU under the Falsified Medicines Directive. In summary, 96% of source countries are now covered either by certification or by listing.

The European Commission, EMA, MHRA and HMA supported the Task Force on Falsified Medicines Directive. This has enabled the task force to achieve progress since June 2012, when the HMA decided to create it.

An overview was also given of the Proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use .

3. Meeting of the Competent Authorities for Medical Devices, Vilnius 26–27 September, 2013

The essential issues discussed during the meeting are as follows:

- The functionality of the Competent Authorities for Medical Devices (CAMD) was reviewed. Currently the purposes of these meetings are to raise the most important questions regarding medical device regulation and legislation and to exchange experience regarding implementation of medical device legislation. However, in view of the strengthening of the legislative system regulating medical devices, the CAMD has to become more effective. A Task force on this question has been established.
- The Joint Plan for immediate actions, which was adopted by the Commission in view of the incident with breast implants, was reviewed. Under this plan the activities of notified bodies for medical devices had to be reviewed and steps to be taken to strengthen the designation and surveillance of the notified bodies .
- Newly proposed regulations on medical devices were discussed. The most important questions raised by Member States concerned post-market monitoring of medical devices, the proper use and functionality of the medical devices database and joint audits of notified bodies.

4. Joint Chief Medical and Nursing Officers meeting, Vilnius 7 October 2013

The meeting of EU Chief Medical Officers and Chief Nursing Officers was held in Vilnius on 7 October 2013. Discussions during the meeting concentrated on sustainable health systems, advanced nursing practice development, the challenges of vaccination in the EU and youth mental health problems. The following conclusions were agreed:

- Advanced nursing practice improves the outcomes and quality of patient health care. Therefore, chief nursing officers of EU Member States, health-care players and other interested parties have to work towards the vision, principles, educational requirements and action plans of advanced nursing practice.
- The prevalence of infectious disease is a very sensitive problem, as it is a consequence of negative public opinion and general unwillingness to have vaccinations. Hence, it is necessary to raise public awareness of the efficiency, effectiveness and importance of vaccinations. It is also important to apply good practice as regards using safe vaccines and regular vaccination techniques.
- Good mental health is a priority area for action at national and regional level. The greatest attention should be paid to youth mental health promotion and prevention, and particularly the protection of vulnerable groups. Research into the prevalence of mental health problems, risk factors and prevention programming areas must continue.

5. Conference “Mental health: challenges and possibilities”, Vilnius 10–11 October 2013

This expert-level conference explored a range of important mental health issues; a number of evidence-based good practices, which highlighted significant opportunities for the improvement of mental health, were presented. Economic productivity can increase as a result of greater consideration of mental health requirements in policymakers’ decisions, strengthened care in the community and in particular strengthened intersectoral cooperation. The value of exchanging experiences and good practices with a focus on opportunities between EU Member States was underlined.

The following priorities, which play important roles in making mental health systems more responsive to mental health needs in the population and to developing partnership action with other sectors, were identified at the conference:

- Keeping in mind the number of people with mental health problems, their social inclusion, success in learning, access to and participation in labour markets are closely related to the sustainability of health and social systems.

- Mental health promotion and prevention of mental disorders, which build resilience, strengthen protection and reduce risk factors, create healthy life environments and focus particularly on vulnerable groups, should be strengthened by the actions of health-care systems in partnership with relevant non-health sectors.
- Mental health services need to be accessible and affordable and available in community settings; opportunities to increase competence should be given to general as well as specialised health-care practitioners.
- Strengthening the mental-health literacy of citizens can enable them to take care of their mental health. There is a great need for improvement in the understanding of mental health and illness and information about the mental health status of the population. Empowerment of people with mental health problems and promotion of their rights can put an end to their stigmatisation and to discrimination against them.

About 200 participants attended the conference, including delegates from Member States and from countries belonging to the European Free Trade Association and the European Union Eastern Partnership. The conference was co-funded by the Lithuanian Presidency and the European Commission (2nd Programme of Community Action in the field of Health).

6. Conference “National Activities Related to Rare Diseases” Vilnius 14 November 2013

The conference “National Activities Related to Rare Diseases” was held in Vilnius on 14 November 2013. The Ministry of Health of the Republic of Lithuania, Vilnius University and the Lithuanian University of Health Sciences organised the conference, in cooperation with the European Commission and EURORDIS.

Participants shared their experience in the management of rare diseases, implementation of national plans and strategies with regard to rare diseases, progress in the establishment of rare-disease centres, readiness to participate in the activities of European reference networks, research in the area of rare diseases, and examination of difficult clinical cases of rare diseases.

The structure of the conference included two plenary sessions and two parallel workshops. During the plenary sessions, participants were introduced to national activities on rare diseases, recent developments in rare-disease policy at national and European levels, and best practices of other countries. Parallel workshops included discussions on implementing nationwide screening for rare diseases, on coordinating research into rare diseases and on health care for patients with rare diseases.

The outcomes of the conference emphasised that society must be made aware of rare diseases, and their early diagnosis as well as quality treatment, nursing, rehabilitation, social support, and prevention must be ensured using all available scientific and clinical experience, optimising systems for providing personal health-care services, medicines and medical devices, and using these resources rationally.

The discussions also noted that the diagnosis of rare diseases and the development of medicinal products for their treatment are long and very expensive processes. Therefore, best practice must be shared among countries and mutual cooperation in this area between scientists, health-care specialists, patients and pharmacy representatives must be promoted.

The outcomes of the conference should provide a strong impetus for the provision of quality and timely health-care services both to patients with rare diseases and to their families.

7. Conference “Sustainable Health Systems for Inclusive Growth in Europe”, Vilnius 19–20 November 2013

A total of 381 participants from 34 countries from various governmental and non-governmental organisations attended the conference, including speakers and guests from the European Commission, World Health Organisation, European Union Member States and European Union Eastern Partnership States.

The Conference featured five thematic blocks:

- Sustainable health systems: visions and strategies
- Sustainable economic growth through better health

- Taking stock: health and health-care inequalities in Europe
- Improving health system productivity: scope for reform
- Sustainable health systems for the future

A closed session hosted by the Ministry of Health of the Republic of Lithuania was also part of the conference. Over 40 participants from the Health Ministries of Member States, the European Union Eastern Partnership States and European non-governmental organisations discussed the topic “Universal coverage: from political principles to reality“.

The conference closed with the adoption of the Vilnius Declaration. The declaration calls on European Union governments and the European Union to take immediate action:

- to increase investment in health promotion and disease prevention;
- to ensure universal access to high-quality, people-centred health services;
- to ensure that health system reforms, including workforce planning, are evidence-based and focus on cost-effectiveness, sustainability and good governance.