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COUNCIL

Council conclusions on the European Pact for Mental Health and Well-being: results and future action

(2011/C 202/01)

THE COUNCIL OF THE EUROPEAN UNION

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, Union action is to complement national policies and be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health; it is also to encourage cooperation between Member States in those areas where Member States, in liaison with the Commission, coordinate among themselves their policies and programmes, and the Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation;

2. RECALLS the Commission's Green Paper of 14 October 2005 on 'Improving the mental health of the population — Towards a strategy on mental health for the European Union';

3. RECALLS the declaration of the European Ministerial Conference of the World Health Organisation (WHO) of 15 January 2005 on facing the challenges of mental health in Europe and building solutions;

4. RECALLS the EU high-level conference 'Together for Mental Health and Well-Being' held in Brussels on 13 June 2008, which established the European Pact for Mental Health and Well-Being;

5. RECALLS the 2010 Report of the WHO on Mental Health and Development: 'Targeting people with mental health conditions as a vulnerable group' that was welcomed by the United Nations General Assembly Resolution 65/95 of 1 December 2010 on global health and foreign policy;

6. RECALLS the Europe 2020 Strategy's Flagship Initiative 'European Platform against Poverty', which states that on almost every account people with mental health problems are among the most excluded groups in society and they consistently identify stigmatisation, discrimination and exclusion as major barriers to health, welfare and quality of life;

7. RECALLS the Europe 2020 Strategy's Flagship Initiative 'An agenda for new skills and jobs' and the Communication from the Commission on a European contribution towards full employment [1], which states that in order to raise employment rates substantially workers' physical and mental health need also to be taken into account to address the demands of today's working careers, which are characterised by more transitions between more intense and demanding jobs and by new forms of work organisation;

8. RECALLS the Conference 'Discovery research in neuropsychiatry: depression, anxiety and schizophrenia in focus' held in Budapest on 18-19 March 2011;

9. RECOGNISES that mental well-being is an essential constituent of health and quality of life, and a prerequisite for the ability to learn, work and contribute to social life;

10. RECOGNISES that according to recent research evidence a high level of mental health and well-being of the population is an important factor for the economy, and that mental disorders lead to economic loss for instance through lower business productivity, lower participation in employment, and costs to individuals, families, and communities dealing with mental disorders;

[1] COM(2010) 682 final.

11. RECOGNISES that mental disorders are disabling and represent the greatest share of disability-adjusted life years in the EU, depression and anxiety being the leading causes of that burden;

12. RECOGNISES that according to WHO-estimations, mental disorders affect every fourth citizen at least once during their life and can be found in more than 10 % of the EU population during any given year;

13. RECOGNISES that suicide remains a significant cause of premature death in Europe, with over 50 000 deaths a year in the EU, and that in nine out of ten cases it is preceded by the development of mental disorders;

14. RECOGNISES that considerable inequalities in mental health status exist between Member States and within Member States and also between social groups of which socioeconomically disadvantaged groups are the most vulnerable;

15. RECOGNISES that the determinants of mental health and well-being, such as social exclusion, poverty, unemployment, poor housing and bad working conditions, problems in education, child abuse, neglect and maltreatment, gender inequalities as well as risk factors such as alcohol and drug abuse are multifactorial, and can often be found outside health systems, and that therefore improving mental health and well-being in the population requires innovative partnerships between the health sector and other sectors such as social affairs, housing, employment and education;

16. RECOGNISES the importance of educational institutions and workplaces as settings for actions in the field of mental health and well-being, as well as the benefits they can gain from such actions for their own objectives;

17. RECOGNISES that authorities and other actors at regional and local levels play a key role in action for mental health and well-being, both as agents for improving mental well-being in their own right, and as promoters of participation from other sectors and communities;

18. RECOGNISES that users of mental health services and their family members, carers as well as their organisations have a specific and valuable expertise to contribute and should be involved in policy action on mental health and well-being;

19. RECOGNISES the need for research on mental health and well-being and mental disorders and WELCOMES the contribution that EU Research Framework Programmes have made to this;

20. WELCOMES the results of the five thematic conferences organised under the European Pact for Mental Health and Well-Being as follows [1]:

— the Conference on 'Promotion of Mental Health and Well-being of Children and Young People — Making it Happen' held in Stockholm on 29-30 September 2009,

— the Conference on 'Prevention of Depression and Suicide — Making it Happen' held in Budapest on 10-11 December 2009,

— the Conference on 'Mental Health and Well-Being in Older People — Making it Happen' held in Madrid 28-29 June 2010,

— the Conference on 'Promoting Social Inclusion and Combating Stigma for Better Mental Health and Well-being' held in Lisbon on 8-9 November 2010,

— the Conference on 'Promoting Mental Health and Well-being at Workplaces' held in Berlin on 3-4 March 2011.

21. INVITES Member States to:

— make mental health and well-being a priority of their health policies and to develop strategies and/or action plans on mental health including depression and suicide prevention,

— include the prevention of mental disorders and the promotion of mental health and well-being as an essential part of these strategies and/or action plans, to be carried out in partnership with the relevant stakeholders and other policy sectors,

— improve social determinants and infrastructure which support mental well-being and improve access to this infrastructure for people suffering from mental disorders,

— promote, where possible and relevant, community-based, socially-inclusive treatment and care models,

— take measures against the stigmatisation and exclusion of and discrimination against people with mental health problems and to promote their social inclusion and their access to education, training, housing and work,

[1] The documents of the thematic conferences are available here: http://ec.europa.eu/health/mental_health/policy/conferences/index_en.htm

— make best use of the possibilities offered by the Structural Funds in the field of mental health in particular for the reform and further improvement of their mental health systems without prejudice to the future financial framework,

— use the potential offered by technology applications, including e-Health, for improving mental health systems and services, prevention of mental disorders and the promotion of well-being,

— take steps towards greater involvement of the health and social sectors along with social partners in the field of mental health and well-being at the workplace, to support and complement employer-led programmes where appropriate,

— support activities (e.g. training programmes) that enable professionals and managers particularly in healthcare, social care, and workplaces to deal with matters concerning mental well-being and mental disorders,

— strengthen mental health promotion of children and young people by supporting positive parenting skills, holistic school approaches to reduce bullying and to increase social and emotional competences as well as supporting families where a parent has a mental disorder.

22. INVITES Member States and the Commission to:

— continue the cooperation as a follow-up to the European Pact for Mental Health and Well-being,

— set up a Joint Action on Mental Health and Well-being under the EU Public Health Programme 2008-2013 providing a platform for exchange of views, cooperation and coordination between Member States, to identify evidence-based best policy approaches and practices and analyse activities in particular in the following areas:

— tackling mental disorders through health and social systems,

— taking evidence-based measures against depression,

— building innovative partnerships between the health and other relevant sectors (e.g. social, education, employment) to analyse policy impact on mental health, to address mental health problems of vulnerable groups and the links between poverty and mental health problems, to address suicide prevention, to promote mental health and well-being and to prevent mental health disorders in different settings, such as workplaces and educational settings,

— managing the evolution of community-based and socially-inclusive approaches to mental health,

— improving data and evidence on the mental health status in populations,

— support interdisciplinary research on mental health;

— make optimal use of the World Mental Health Day at European, national and regional level through appropriate awareness raising actions.

23. INVITES the Commission to:

— continue addressing mental health and well-being in partnership with EU health policy and other policy areas,

— further develop the European Compass for Action on Mental Health and Well-being,

— support Member States, by providing data on the mental health status in the population, and carrying out research on the fields of mental health and its determinants, including the health, economic and social costs caused by mental health problems, taking into account the work done by WHO and OECD,

— present a report on the outcomes of the Joint Action, including an inventory of evidence-based actions in mental health care, social inclusion, prevention and promotion, as well as a reflection on possible future policy actions as a follow-up to the European Pact for Mental Health and Well-being.

Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward

(2011/C 202/02)

THE COUNCIL OF THE EUROPEAN UNION

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, Union action is to complement national policies and be directed towards improving public health by covering in particular the fight against the major health scourges; it is also to encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and respect the responsibilities of the Member States for the organisation and delivery of health services and medical care;

2. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, the Member States, in liaison with the Commission, are to coordinate among themselves their policies and programmes;

3. RECALLS Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community ([1]), which requires timely scientific analysis in order for effective Community action to be undertaken;

4. RECALLS Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control ([2]), which supports existing activities, such as relevant Community action programmes in the public health sector, with regard to the prevention and control of communicable diseases, epidemiological surveillance, training programmes and early warning and response mechanisms, and should foster the exchange of best practices and experience with regard to vaccination programmes;

5. RECOGNISES that while childhood immunisation is the responsibility of individual Member States and various vaccination schemes exist in the EU as regards their professional content, their mandatory or voluntary character or their financing, there is added value in addressing this issue at a European level;

6. RECOGNISES that possible joint efforts to improve childhood vaccination may also benefit from improved synergies with other EU policy areas with special regard to vulnerable groups, for example the Roma in certain Member States;

7. WELCOMES the outcomes of the expert level conference 'For a Healthy Future of Our Children — Childhood Immunisation', held in Budapest on 3-4 March 2011, where participants examined successes and challenges of childhood immunisation in the European Union and underlined the need to achieve and maintain timely, high childhood immunisation coverage in both general and under-vaccinated populations; having quality data for monitoring coverage and surveillance of vaccine-preventable diseases at sub-national, national and EU levels; and co-ordinating and refining communication strategies to target under-vaccinated population groups or those who are sceptical about the benefits of vaccination;

8. NOTES that while childhood immunisation programmes have been instrumental in controlling infectious diseases in Europe, many challenges still remain;

9. RECALLS that the most effective and economical way of preventing infectious diseases is through vaccination, where vaccination exists;

10. NOTES that increasing mobility and migration raise a number of health related questions, which are also relevant for childhood immunisation;

11. UNDERLINES that vaccines have led to the control, lower incidence and even elimination of diseases in Europe that in the past caused death and disability for millions of people, and that the global eradication of smallpox and the elimination of poliomyelitis from most countries in the world are excellent examples of successful vaccination programmes;

12. NOTES that measles and rubella epidemics continue to occur in several European countries and UNDERLINES that Europe failed to meet the goal of eliminating measles and rubella by 2010, because of lower-than-required vaccination coverage prevailing at sub-national levels, and therefore RECALLS the resolution of the World Health Organisation (WHO) of 16 September 2010 on renewed commitment to the elimination of measles and rubella and prevention of congenital rubella syndrome by 2015 and sustained support for polio-free status in the WHO European Region;

13. UNDERLINES the importance of identifying and addressing population groups at increased risk of vaccine-preventable diseases and at the same time NOTES the significance of the fact that susceptible populations differ from one country or region to another;

([1]) OJ L 268, 3.10.1998, p. 1.
([2]) OJ L 142, 30.4.2004, p. 1.

14. INVITES Member States to:

— assess and map barriers and challenges affecting access to, and reach of, vaccination services and refine and/or strengthen their national or sub-national strategies accordingly,

— make efforts to maintain and strengthen their processes and procedures for offering vaccines to children with unknown or uncertain vaccination history,

— make efforts to maintain and strengthen public trust in childhood immunisation programmes and the benefits of vaccination,

— make efforts to increase health professionals' awareness of the benefits of vaccines and strengthen their support for immunisation programmes,

— reinforce education and training of health professionals and other relevant experts on childhood immunisation,

— co-operate closely with local communities, involving all relevant actors and networks,

— identify under-vaccinated groups and ensure their equitable access to childhood vaccinations,

— ensure close co-operation of relevant public health, paediatric and primary care services for the continuous follow-up and evaluation of individual vaccination records, including the timeliness of vaccine administration from birth until adulthood,

— make efforts to improve laboratory capacity in the field of diagnostics and surveillance of the vaccine-preventable diseases,

— consider the use, where appropriate, of innovative vaccines proven to be effective and cost-effective, to address unmet public health needs,

— consider introducing or further developing immunisation information systems, including improved registration, where applicable, and pharmacovigilance systems;

15. INVITES Member States and the Commission to:

— further develop co-operation among national and sub-national immunisation services, further refine and co-ordinate monitoring of vaccination coverage as well as reporting systems,

— make efforts to reinforce the surveillance of vaccine-preventable diseases; refine information systems as well as immunisation registers, where applicable,

— consider shaping the methodology for the use of common indicators for vaccination to support EU-wide data collection in close collaboration with the WHO,

— consider which systems and procedures could help to ensure proper continuity of immunisation of individuals when changing the place of residence between Member States,

— foster the improvement of immunisation programmes,

— co-operate in tailoring approaches and communication strategies in engaging with the concerns of those who are sceptical about the benefits of vaccination,

— share experiences and best practices to improve vaccination coverage of children against vaccine-preventable diseases in general, as well as amongst under-vaccinated population groups,

— in order to facilitate the exchange of information between vaccine service providers, to identify with the support of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) a non-exhaustive list of elements suggested for inclusion in national, sub-national immunisation cards or health booklets. This has to be done in due respect of Member States' own public health policies while taking into account the elements for vaccination certificates listed in Annex 6 to the WHO International Health Regulations. This information should be easily understandable within the EU;

16. INVITES the Commission to:

— ensure synergy between the promotion of childhood vaccination and the implementation of relevant EU legislation and policies, while fully respecting national competences,

— examine with the ECDC and the EMA in close cooperation with and taking into account the work done so far by the WHO, the options to

  — identify commonly agreed guidance and methodologies for reaching out to broader populations, including evidence-based links between vaccination and diseases,

  — identify commonly agreed methodologies for monitoring and assessing vaccination coverage and real level of protection in the community,

— identify methodologies for monitoring of public support for vaccination programmes,

— facilitate the development and implementation of communication strategies aimed at engaging with persons who are sceptical about the benefits of vaccination providing clear, factual information about the advantages of vaccination,

— provide guidelines and tools to help Member States to design efficient communication messages,

— develop multilingual EU vaccination resources for health care professionals and the public with the aim to provide objective, easily accessible (web and/or paper based) and evidence-based information on vaccines and immunisation schedules including vaccines used in the Member States,

— facilitate regional and EU-wide projects for increasing access to vaccination for transnational under-vaccinated groups.

Council conclusions on innovation in the medical device sector

(2011/C 202/03)

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLING the Council conclusions of 26 June 2002 [1] and of 2 December 2003 [2] and the subsequent amendments to the legislative framework for medical devices [3];

2. DRAWING ATTENTION TO the conclusions [4] of the High Level Health Conference on innovation in medical technology held in Brussels on 22 March 2011;

3. BEARING IN MIND:

— the major long-term societal challenges facing Europe, such as an ageing population, which will call for innovative healthcare systems,

— the importance of medical devices in health- and social care, their contribution to improving the level of health protection and the fact that medical devices today account for a significant amount of public health expenditure,

— that the development of medical devices may deliver innovative solutions for diagnosis, prevention, treatment and rehabilitation, that could improve health and quality of life for patients, disabled persons, and their families, could contribute to mitigating the shortage of healthcare professionals and could contribute to addressing the sustainability of healthcare systems,

— that innovation in medical devices should contribute to the continued improvement of patient and user safety,

— the European Innovation Partnership on Active and Healthy Ageing launched by the European Commission with the aim of tackling societal challenges through innovation,

— that the medical device sector in Europe comprises around 18 000 small and medium-sized enterprises (SMEs) and that this fact must be considered when future legislative and administrative measures are being adopted at European Union level and at national level,

— the need to adapt EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent and sustainable regulatory framework, which is central to fostering the development of safe, effective and innovative medical devices for the benefit of European patients and healthcare professionals,

— the importance of having the EU continue to play a leading role in the field of international regulatory convergence and best regulatory practice regarding medical devices, for instance through the Global Harmonisation Task Force, and be party to global initiatives such as global vigilance and global instruments for improving identification and traceability of medical devices;

4. STRESSING that in order for innovation to benefit patients, healthcare professionals, industry and society:

— innovation should be increasingly patient- and user-centred and demand-driven, e.g. through increased involvement of patients, their families and users in the research, innovation and development processes in order to improve individual health and quality of life,

— innovation should be a more integrated process, building on experience and knowledge acquired in other sectors, such as IT and the development of new materials,

— innovation should be based on a holistic approach (i.e. it should take into account the whole healthcare process and all patients' needs — physical, social, psychological, etc.),

— innovation should focus on public health priorities and healthcare needs inter alia in order to improve cost-effectiveness,

— there is a need to increase research in order to identify public health needs and priorities still to be addressed and to better define patients' medical needs,

— future legislative actions in this area must, when adapting the European regulatory framework, specifically aim to increase patients' safety while at the same time creating a sustainable legislative framework favourable to medical device innovation that can contribute to a healthy, active and independent life;

5. INVITES THE COMMISSION AND THE MEMBER STATES to:

— promote measures that make use of valuable innovative solutions with proven benefit, and improve information and training for healthcare professionals, patients and patients' families regarding their use,

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[1] Doc. 10060/02.
[2] Doc. 14747/03.
[3] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21).
[4] http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf

— further map and share national and European best practices regarding innovation and enhance the deployment of research to facilitate, where relevant, the transfer of experiences gained in national or regional studies and pilot projects to the multinational, multiregional or European level,

— ensure stronger collaboration and dialogue between the various actors involved in the innovation process (e.g. through networks and clusters),

— promote valuable innovation through public procurement policies while taking into account safety aspects,

— take existing measures into account, and when necessary consider further measures which enhance the capacity for innovation, for instance the use of innovative funding systems directed, in particular, towards SMEs and that are designed to make optimum use of resources from the private and public sectors,

— pay particular attention to interoperability and safety issues related to the integration of medical devices in e-Health systems, especially Personal Health Systems and mobile health systems (m-Health) while bearing in mind that the deployment of health ICT systems is entirely a matter of national competence,

— encourage better consideration of the needs of patients and healthcare professionals in the design process of medical devices,

— consider further improving the involvement of patients and healthcare professionals in vigilance in order to improve the system of notification of adverse incidents relating to the use of medical devices,

— promote early dialogue between manufacturers, scientific and clinical experts, competent authorities and, where appropriate, notified bodies regarding 'new products' in particular, and their classification,

— enhance cooperation between authorities of relevant sectors, where appropriate,

— examine how and at which level the promotion of medical devices can be regulated in the most effective and efficient way;

6. INVITES THE COMMISSION to take the following considerations into account in the course of its future legislative work:

— mechanisms are needed to enhance reliability, predictability, speed and transparency in decision-making, and make sure that it is based on scientifically validated data,

— the system of risk based classification should be improved (in particular for *in vitro* diagnostic medical devices and 'new products' as appropriate),

— clinical data from pre-marketing studies and post-marketing experience (vigilance reports, post-marketing clinical follow-up, European registers) must be collected in a transparent way and to a greater extent in order to provide the clinical evidence which fulfils regulatory purposes and can, where appropriate, assist health technology assessment, whilst fully recognising and respecting national competences for the latter. Consideration should also be given to methods for ensuring that notified bodies are better equipped with the appropriate expertise to analyse such data in a meaningful way,

— there is a need for clearer and simpler rules defining the obligations and responsibilities of all economic operators and the role of other stakeholders (in particular national competent authorities and notified bodies),

— the development of a modern IT infrastructure for a central and publicly available database must be further pursued with a view to providing key information about medical devices, relevant economic operators, certificates, clinical investigations and field safety corrective actions. In this context, the possibility of introducing a system to improve the traceability of devices, thus enhancing safety, must be studied,

— where necessary, clarification should be made regarding the definition of medical devices and the criteria for their classification,

— in addition, a simple and rapid mechanism must be set up for accelerated adoption of binding and consistent decisions and the implementation thereof on the determination of products as medical devices and the classification of medical devices in order to address the growing number of 'borderline' cases between medical devices and other products subject to different regulatory frameworks (the framework for pharmaceuticals in particular, but also those for cosmetics, aesthetic products, food or biocides),

— as regards the oversight of notified bodies, there is a need to continue to improve the harmonised list of criteria to be satisfied before their designation. In particular the designation process should ensure that they are designated only for the assessment of devices or technologies which correspond to their proven expertise and competencies. The process should also address the need to improve monitoring of notified bodies by national authorities in order to ensure an EU-wide comparable and high-level performance of notified bodies, in this context an enhanced European coordination between competent authorities as well as between notified bodies should also be considered,

— the vigilance system for medical devices must be further developed in order to allow a coordinated analysis and a rapid and coherent EU-wide response to safety issues, if needed,

— it is desirable to consider a European coordination mechanism founded on a clear legal basis and mandate in order to ensure efficient and effective coordination between national authorities while creating a level playing field. Synergies with existing bodies with relevant expertise should be explored when deciding on the mechanisms for such coordination. Consideration should also be given to which activities are best carried out in cooperation between Member States,

— as the medical device sector is a global one, a stronger coordination with international partners is desirable in order to ensure that medical devices are manufactured according to high safety requirements worldwide,

— there is a need for a sustainable legislative framework for medical devices which ensures safety and promotes innovation,

— it should be considered how to address regulatory gaps in the system, for instance in relation to medical devices manufactured utilising non-viable human cells and tissues,

— the need for introducing more harmonised provisions relating to the content, presentation and comprehensibility of the instructions for use of medical devices should be further considered.

Council conclusions: towards modern, responsive and sustainable health systems

(2011/C 202/04)

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities; as well as Union action is to complement national policies and be directed towards improving public health; it is also to encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care;

2. RECALLS the Council conclusions on the Commission White Paper 'Together for Health: A Strategic Approach for the EU, 2008-2013' adopted on 6 December 2007;

3. RECALLS the Council conclusions on common values and principles in EU health systems adopted on 2 June 2006 [1], and particularly the overarching values of universality, access to good quality care, equity and solidarity;

4. RECALLS the Tallinn Charter on Health Systems for Health and Wealth, signed on 27 June 2008 under the auspices of the World Health Organisation (WHO);

5. RECALLS the Joint Report on Health Systems prepared by the European Commission (EC) and the Economic Policy Committee (EPC) finalised on 23 November 2010, as well as the Council conclusions on the EC-EPC Joint Report on Health Systems, adopted on 7 December 2010;

6. ACKNOWLEDGES the work carried out by the Social Protection Committee (SPC) and RECALLS the objectives agreed within the framework of the Open Method of Coordination for social protection and social inclusion at the European Council of March 2006 to ensure accessible, high-quality and sustainable healthcare and long-term care;

7. RECALLS the discussion at the Informal Meeting of Ministers of Health held in Gödöllő on 4-5 April 2011 on 'Patient and Professional Pathways in Europe — Investing in the health systems of the future';

8. RECALLS the Europe 2020 Strategy and WELCOMES the Commission's initiative in bringing forward the pilot European Innovation Partnership on 'Active and Healthy Ageing' and its ongoing work;

9. RECOGNISES that Member States face common challenges due to an ageing population, changing population needs, increasing patient expectations, rapid technology diffusion and growing costs of healthcare as well as due to the current uncertain and fragile economic climate resulting particularly from the recent global economic and financial crisis which is progressively limiting the resources available to Member States' health systems. The growing rise of chronic diseases represents one of the major challenges to health systems;

10. RECOGNISES that, whilst ensuring equitable access to high quality healthcare services in circumstances of scarce economic and other resources has always been a key question, at present it is the scale and urgency of the situation that is changing and, if unaddressed, it could become a crucial factor in the future economic and social landscape of the EU;

11. RECOGNISES the need for smart and responsible innovation, including social and organisational innovation, to balance future demands against affordable and sustainable resources in order to be able to respond to all these challenges;

12. CALLS for the need that the health sector should play an adequate role in the implementation of the Europe 2020 Strategy. Investments in health should be acknowledged as a contributor to economic growth. While health is a value in itself, it is also a pre-condition to achieve economic growth;

13. EMPHASISES that in order to create modern, responsive, efficient, effective and financially sustainable health systems that provide equitable access to health services for all, European Structural Fund resources can be used, without prejudice to the negotiations on the future financial framework, in complementing the financing of health sector development of eligible regions of Member States, including inter alia capital investments, particularly because:

— achieving social cohesion, reducing major disparities and closing serious health gaps existing between and within Member States are of utmost importance,

— developing 'new generation' approaches to healthcare will require appropriate funding to foster transformation of health systems and rebalance investment towards new and sustainable care models and facilities;

[1] OJ C 146, 22.6.2006, p. 1.

14. EMPHASISES the fundamental importance of the effectiveness of investments in the health systems of the future, which should be measured and monitored by the respective Member States;

15. RECOGNISES the importance of evidence-based policy-making and decision-making processes supported by adequate health information systems;

16. RECOGNISES that, in the European Union, there is a need for sharing evidence on health systems' modernisation and of new healthcare approaches;

17. RECOGNISES that health promotion and disease prevention are key factors for the long-term sustainability of health systems;

18. EMPHASISES that the availability of sufficient numbers of adequately trained health professionals in each Member State, is a key pre-condition for the operation of modern, dynamic health systems and each Member State should fulfil its needs and adhere to the WHO Global Code of Practice on international recruitment;

19. EMPHASISES the need to join forces and enter into more coordinated EU-level cooperation in order to support Member States, when appropriate, in their efforts to ensure that their health systems meet future challenges, building on results achieved through national and EU initiatives, as well as activities carried out by intergovernmental organisations, such as the Organisation for Economic Cooperation and Development (OECD) and the WHO;

20. UNDERLINES the leading role of Ministers of Health in developing and pursuing effective, health policy-driven approaches in order to adequately address macroeconomic, health and societal challenges including those related to ageing population, and ensure future long-term health sector strategies, with particular emphasis on health sector investment and human resource strategies;

21. INVITES Member States to:

— reinforce their commitment to play an active role in developing effective, health policy-driven approaches to adequately address macroeconomic challenges and health and societal challenges,

— ensure that health is adequately addressed in the National Reform Programmes submitted by Member States within the framework of the Europe 2020 Strategy,

— reposition the perception of health policy, making it more visible when macroeconomic issues are at stake and shifting it from being regarded as just an expenditure post to being an acknowledged contributor of economic growth,

— consider innovative approaches and models of healthcare responding to challenges, and develop future long-term health sector strategies, with particular emphasis on effective investment in the health sector and in human resources with the aim of moving away from hospital-centred systems towards integrated care systems, enhancing equitable access to high quality care and reducing inequalities,

— further strengthen health promotion and disease prevention in an integrated manner in the spirit of the Health in All Policies approach,

— foster health technology assessments and ensure smarter use of e-health solutions to ensure value for money and benefits for health and health systems,

— make smarter use of EU financial programmes, including inter alia Structural Funds, which can contribute to health system innovation and to reducing health inequalities, and can trigger further economic growth;

22. INVITES Member States and the Commission to:

— initiate a reflection process under the auspices of the Working Party on Public Health at Senior Level aiming to identify effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems,

— in order to launch the reflection process and accomplish its objectives:

  — request the Working Party on Public Health at Senior Level to steer the reflection process, set up its roadmap and develop its modalities,

  — request the Working Party on Public Health at Senior Level to hold regular dialogue with the EPC and the SPC,

  — facilitate access for Member States to informal and independent advice from experts in policy areas relevant to this reflection process,

— include in this reflection process the following objectives in particular:

  — enhancing the adequate representation of health in the framework of the Europe 2020 Strategy and in the process of the European Semester,

  — sharing and analysing experiences, best practices, to build up success factors for the effective use of Structural Funds for health investments,

— sharing experiences, best practices and expertise in understanding and adequately responding to society's growing and changing health needs particularly due to ageing population, and designing health sector investments effectively and efficiently,

— cooperating on measuring and monitoring the effectiveness of health investments,

— taking into account programmes, data, knowledge, evidence and expertise existing within the EU, in intergovernmental organisations, particularly the WHO and the OECD, and in the Member States, thus avoiding duplication of efforts;

23. INVITES the Commission to:

— support Member States in initiating and implementing the reflection process,

— support the reflection process through appropriate measures, including by facilitating the access to informal and independent multisectoral expert advice to be provided on request to Member States and/or the Working Party on Public Health at Senior Level,

— promote an adequate role of the health sector in the implementation of the Europe 2020 Strategy, and support regular follow-up discussions with Member States on the state of play,

— stress the major economic role of the health sector, aiming to shift health from being regarded as just an expenditure post to being an acknowledged contributor of economic growth,

— provide effective tools and methodologies for Member States for the assessment of the performance of health systems,

— promote new ways of supporting Member States in addressing their future health investment needs,

— present regular reports to the Council to contribute to the reflection process, the first report being submitted by the end of 2012.

AGREEMENT

between the Member States of the European Union, meeting within the Council, regarding the protection of classified information exchanged in the interests of the European Union

(2011/C 202/05)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION, MEETING WITHIN THE COUNCIL,

Whereas:

(1) The Member States of the European Union (hereinafter referred to as 'the Parties') recognise that full and effective consultation and cooperation may require the exchange of classified information among them in the interests of the European Union, and between them and European Union institutions or agencies, bodies or offices established by the latter.

(2) The Parties share the common desire to contribute to putting in place a coherent and comprehensive general framework for the protection of classified information originating in the Parties in the interests of the European Union, in European Union institutions, or in agencies, bodies or offices established by the latter or received from third States or international organisations in this context.

(3) The Parties are conscious that access to and exchanges of such classified information require appropriate security measures for its protection,

HAVE AGREED AS FOLLOWS:

Article 1

The purpose of this Agreement is to ensure the protection by the Parties of classified information:

(a) originating in European Union institutions, or in agencies, bodies or offices established by the latter and provided to or exchanged with the Parties;

(b) originating in the Parties and provided to or exchanged with European Union institutions, or agencies, bodies or offices established by the latter;

(c) originating in the Parties in order to be provided or exchanged between them in the interests of the European Union and marked to indicate that it is subject to this Agreement;

(d) received by European Union institutions or agencies, bodies or offices established by the latter from third States or international organisations and provided to or exchanged with the Parties.

Article 2

For the purposes of this Agreement, 'classified information' shall mean any information or material, in any form, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union, or of one or more of the Member States, and which bears one of the following EU classification markings or a corresponding classification marking as set out in the Annex:

— 'TRÈS SECRET UE/EU TOP SECRET'. This marking is applied to information and material the unauthorised disclosure of which could cause exceptionally grave prejudice to the essential interests of the European Union or of one or more of the Member States.

— 'SECRET UE/EU SECRET'. This marking is applied to information and material the unauthorised disclosure of which could seriously harm the essential interests of the European Union or of one or more of the Member States.

— 'CONFIDENTIEL UE/EU CONFIDENTIAL'. This marking is applied to information and material the unauthorised disclosure of which could harm the essential interests of the European Union or of one or more of the Member States.

— 'RESTREINT UE/EU RESTRICTED'. This marking is applied to information and material the unauthorised disclosure of which could be disadvantageous to the interests of the European Union or of one or more of the Member States.

Article 3

1. The Parties shall take all appropriate measures in accordance with their respective national laws and regulations to ensure that the level of protection afforded to classified information subject to this Agreement is equivalent to that afforded by the security rules of the Council of the European Union for protecting EU classified information bearing a corresponding classification marking as set out in the Annex.

2. Nothing in this Agreement shall cause prejudice to the national laws and regulations of the Parties regarding public access to documents, the protection of personal data or the protection of classified information.

3. The Parties shall notify the depositary for this Agreement of any changes to the security classifications set out in the Annex. Article 11 shall not apply to such notifications.

Article 4

1. Each Party shall ensure that classified information provided or exchanged under this Agreement is not:

(a) downgraded or declassified without the prior written consent of the originator;

(b) used for purposes other than those established by the originator;

(c) disclosed to any third State or international organisation without the prior written consent of the originator and an appropriate agreement or arrangement for the protection of classified information with the third State or international organisation concerned.

2. The principle of originator consent shall be respected by each Party in accordance with its constitutional requirements, national laws and regulations.

Article 5

1. Each Party shall ensure that access to classified information is granted on the basis of the need-to-know principle.

2. The Parties shall guarantee that access to classified information bearing the classification marking 'CONFIDENTIEL UE/EU CONFIDENTIAL' or above or a corresponding classification marking as set out in the Annex is granted only to individuals who hold an appropriate security clearance or who are otherwise duly authorised by virtue of their functions in accordance with national laws and regulations.

3. Each Party shall ensure that all individuals granted access to classified information are informed of their responsibilities to protect such information in accordance with the appropriate security regulations.

4. Upon request, the Parties shall, in accordance with their respective national laws and regulations, provide mutual assistance in carrying out security investigations relating to security clearances.

5. In accordance with its national laws and regulations, each Party shall ensure that any entity under its jurisdiction which may receive or generate classified information is appropriately security cleared and is capable of providing suitable protection, as provided for in Article 3(1), at the appropriate security level.

6. Within the scope of this Agreement, each Party may acknowledge the personnel and facility security clearances issued by another Party.

Article 6

The Parties shall ensure that all classified information within the scope of this Agreement transmitted, exchanged or transferred within or between any of them shall be appropriately protected, as provided for in Article 3(1).

Article 7

Each Party shall ensure that appropriate measures are implemented for the protection, as provided for in Article 3(1), of classified information processed, stored or transmitted in communication and information systems. Such measures shall ensure the confidentiality, integrity, availability and, where applicable, non-repudiation and authenticity of classified information as well as an appropriate level of accountability and traceability of actions in relation to that information.

Article 8

The Parties shall provide one another, upon request, with relevant information about their respective security rules and regulations.

Article 9

1. The Parties shall take all appropriate measures, in accordance with their respective national laws and regulations, to investigate cases where it is known or where there are reasonable grounds for suspecting that classified information within the scope of this Agreement has been compromised or lost.

2. A Party which discovers a compromise or loss shall, through the appropriate channels, immediately inform the originator of such an occurrence and subsequently inform the originator of the final results of the investigation and of the corrective measures taken to prevent a recurrence. Upon request, any other relevant Party may provide investigative assistance.

Article 10

1. This Agreement shall not affect existing agreements or arrangements on the protection or exchange of classified information entered into by any Party.

2. This Agreement shall not preclude the Parties from entering into other agreements or arrangements relating to the protection and exchange of classified information originated by them, provided that such agreements or arrangements do not conflict with this Agreement.

Article 11

This Agreement may be amended by written agreement between the Parties. Any amendment shall enter into force upon notification pursuant to Article 13(2).

Article 12

Any dispute between two or more Parties relating to the interpretation or application of this Agreement shall be settled through consultations between the Parties concerned.

Article 13

1. The Parties shall notify the Secretary-General of the Council of the European Union of the completion of the internal procedures necessary for the entry into force of this Agreement.

2. This Agreement shall enter into force on the first day of the second month following notification to the Secretary-General of the Council of the European Union of the completion of the internal procedures necessary for its entry into force by the last Party to take this step.

3. The Secretary-General of the Council of the European Union shall act as depositary for this Agreement which shall be published in the *Official Journal of the European Union*.

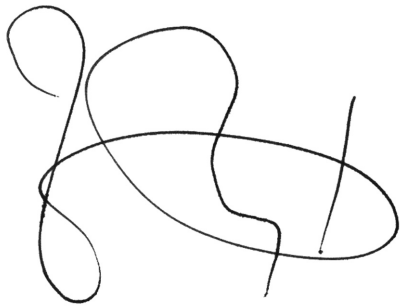
Article 14

This Agreement is drawn up in a single original in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, all 23 texts being equally authentic.

IN WITNESS WHEREOF, the undersigned Representatives of the Governments of the Member States, meeting within the Council, have signed this Agreement.

Done at Brussels on the fourth day of May in the year two thousand and eleven.

Voor de regering van het Koninkrijk België
Pour le gouvernement du Royaume de Belgique
Für die Regierung des Königreichs Belgien



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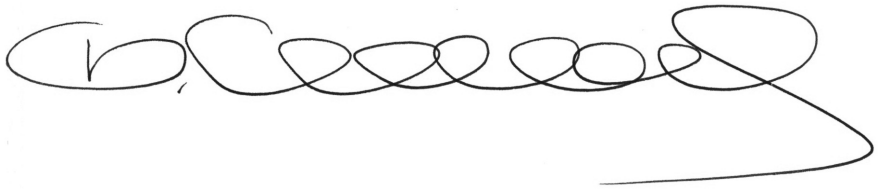

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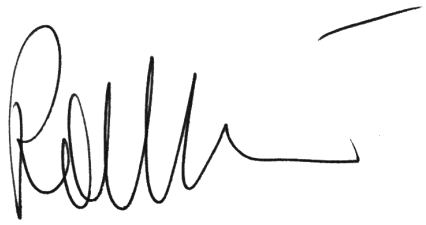
For Kongeriget Danmarks regering

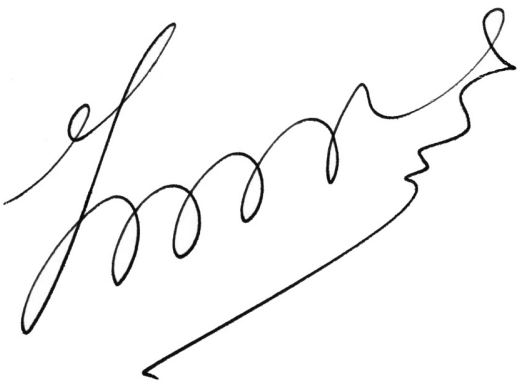
Für die Regierung der Bundesrepublik Deutschland

Eesti Vabariigi valitsuse nimel



Thar ceann Rialtas na hÉireann
For the Government of Ireland

Για την Κυβέρνηση της Ελληνικής Δημοκρατίας



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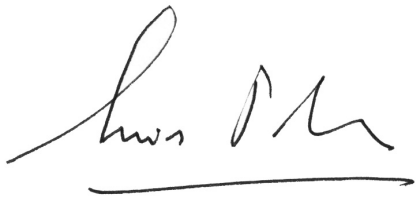

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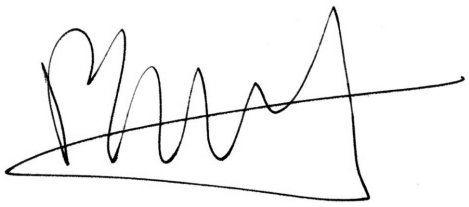

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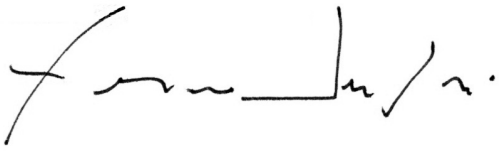

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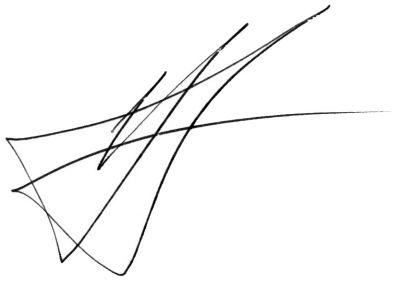

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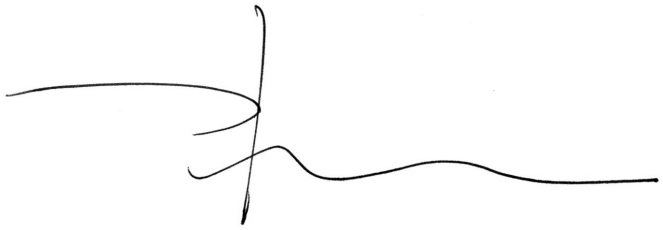

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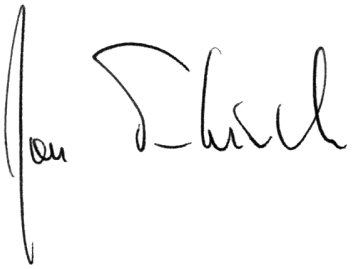

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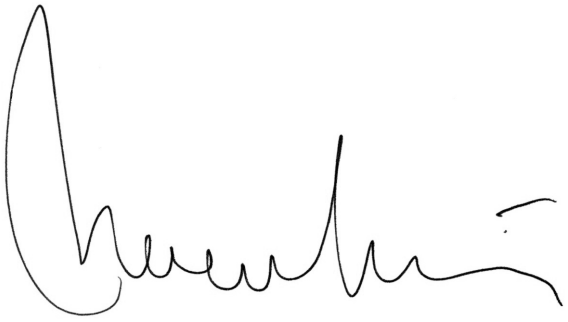
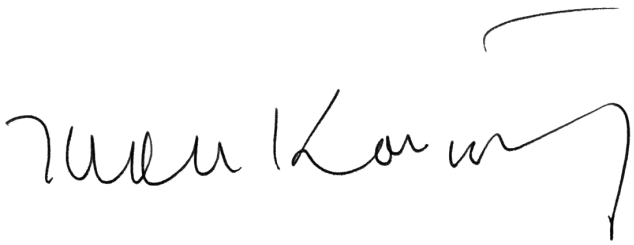


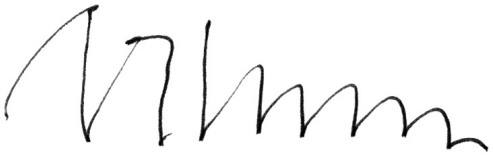
Pentru Guvernul României

Za vlado Republike Slovenije

Za vládu Slovenskej republiky



Suomen tasavallan hallituksen puolesta
För Republiken Finlands regering



För Konungariket Sveriges regering

For the Government of the United Kingdom of Great Britain and Northern Ireland

ANNEX

Equivalence of security classifications

EU	TRÈS SECRET UE/EU TOP SECRET	SECRET UE/EU SECRET	CONFIDENTIEL UE/ EU CONFIDENTIAL	RESTREINT UE/EU RESTRICTED
Belgium	Très Secret (Loi 11.12.1998) Zeer Geheim (Wet 11.12.1998)	Secret (Loi 11.12.1998) Geheim (Wet 11.12.1998)	Confidentiel (Loi 11.12.1998) Vertrouwelijk (Wet 11.12.1998)	*nota below* (1)
Bulgaria	Строго секретно	Секретно	Поверително	За служебно ползване
Czech Republic	Přísně tajné	Tajné	Důvěrné	Vyhrazené
Denmark	Yderst hemmeligt	Hemmeligt	Fortroligt	Til tjenestebrug
Germany	STRENG GEHEIM	GEHEIM	VS (2) — VERTRAULICH	VS — NUR FÜR DEN DIENSTGEBRAUCH
Estonia	Täiesti salajane	Salajane	Konfidentsiaalne	Piiratud
Ireland	Top Secret	Secret	Confidential	Restricted
Greece	Άκρως Απόρρητο Abr: ΑΑΠ	Απόρρητο Abr: (ΑΠ)	Εμπιστευτικό Abr: (ΕΜ)	Περιορισμένης Χρήσης Abr: (ΠΧ)
Spain	SECRETO	RESERVADO	CONFIDENCIAL	DIFUSIÓN LIMITADA
France	Très Secret Défense	Secret Défense	Confidentiel Défense	*nota below* (3)
Italy	Segretissimo	Segreto	Riservatissimo	Riservato
Cyprus	Άκρως Απόρρητο Abr: (ΑΑΠ)	Απόρρητο Abr: (ΑΠ)	Εμπιστευτικό Abr: (ΕΜ)	Περιορισμένης Χρήσης Abr: (ΠΧ)
Latvia	Sevišķi slepeni	Slepeni	Konfidenciāli	Dienesta vajadzībām
Lithuania	Visiškai slaptai	Slaptai	Konfidencialiai	Riboto naudojimo
Luxembourg	Très Secret Lux	Secret Lux	Confidentiel Lux	Restreint Lux
Hungary	Szigorúan titkos!	Titkos!	Bizalmas!	Korlátozott terjesztésű!
Malta	L-Ogħla Segretezza	Sigriet	Kunfidenzjali	Ristrett
Netherlands	Stg. ZEER GEHEIM	Stg. GEHEIM	Stg. CONFIDENTIEEL	Dep. VERTROUWELIJK
Austria	Streng Geheim	Geheim	Vertraulich	Eingeschränkt
Poland	Ściśle tajne	Tajne	Poufne	Zastrzeżone
Portugal	Muito Secreto	Secreto	Confidencial	Reservado
Romania	Strict secret de importanță deosebită	Strict secret	Secret	Secret de serviciu
Slovenia	Strogo tajno	Tajno	Zaupno	Interno
Slovakia	Prísne tajné	Tajné	Dôverné	Vyhradené
Finland	ERITTÄIN SALAINEN YTTERST HEMLIG	SALAINEN HEMLIG	LUOTTAMUKSELLINEN KONFIDENTIELL	KÄYTTÖ RAJOITETTU BEGRÄNSAD TILLGÅNG
Sweden (4)	HEMLIG/TOP SECRET HEMLIG AV SYNNERLIG BETYDELSE FÖR RIKETS SÄKERHET	HEMLIG/SECRET HEMLIG	HEMLIG/CONFIDENTIAL HEMLIG	HEMLIG/RESTRICTED HEMLIG
United Kingdom	Top Secret	Secret	Confidential	Restricted

(1) 'Diffusion Restreinte/Beperkte Verspreiding' is not a security classification in Belgium. Belgium handles and protects 'RESTREINT UE/EU RESTRICTED' information in a manner no less stringent than the standards and procedures described in the security rules of the Council of the European Union.

(2) Germany: VS = 'Verschlusssache'.

(3) France does not use the classification 'RESTREINT' in its national system. France handles and protects 'RESTREINT UE/EU RESTRICTED' information in a manner no less stringent than the standards and procedures described in the security rules of the Council of the European Union.

(4) Sweden: the security classification markings in the top row are used by the defence authorities and the markings in the bottom row by other authorities.

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