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OUTCOME OF THE COUNCIL MEETING

3434th Council meeting

Employment, Social Policy, Health and Consumer Affairs

Employment, Social Policy and Health

Brussels, 7 December 2015

Presidents

Nicolas Schmit
Minister for Minister for Labour, Employment and the Social and Solidarity Economy of Luxembourg
Lydia Mutsch
Minister for Health and Equal Opportunities of Luxembourg
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Minister for Family Affairs and Integration of Luxembourg
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Minister for Social Security of Luxembourg

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ITEMS DEBATED

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- Where declarations, conclusions or resolutions have been formally adopted by the Council, this is indicated in the heading for the item concerned and the text is placed between quotation marks.
- Documents for which references are given in the text are available on the Council's Internet site (http://www.consilium.europa.eu).
- Acts adopted with statements for the Council minutes which may be released to the public are indicated by an asterisk; these statements are available on the Council's Internet site or may be obtained from the Press Office.

OTHER ITEMS APPROVED

COMMON SECURITY AND DEFENCE POLICY

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ITEMS DEBATED

EMPLOYMENT AND SOCIAL POLICY

Women on company boards

The Council was not able to agree on the women on company boards directive.

There is currently no qualified majority on this dossier in the Council. Although there is a broad consensus across the EU in favour of taking measures to improve the gender balance on company boards, some member states prefer to do so at national level. They thus take the view that the proposal does not comply with the principle of subsidiarity.

– ***Work under the Luxembourg presidency***

The presidency had redrafted the text, making it more flexible. National measures are now fully recognised in the draft directive, and the deadlines have been extended.

The flexibility clause (article 4b) would allow member states to pursue the aims of the directive by means of their own choosing and to suspend the directive's procedural requirements, provided that they have already taken equally effective measures or attained progress coming close to the quantitative objectives set in the directive.

Implementation calendar and sunset clause (articles 4b, 9 and 10): the suspension of the application of article 4a, provided for in article 4b, would expire on 31 December 2022 (rather than 31 December 2020) unless certain conditions were met.
If the conditions were not met, member states would be required to ensure the application of the procedural requirements contained in article 4a with effect from 30 September 2023 (rather than 30 September 2021).
Presidency report

Integration of the long-term unemployed into the labour market

The Council reached a political agreement on the recommendation on the integration of the long-term unemployed into the labour market (14361/15).

The Council considers that long-term unemployment is a problem that must be addressed urgently, and the recommendation is intended to establish the right framework to support member states' actions.

Modelled on the youth initiative (Youth Guarantee), the proposed recommendation is targeted at a group that was hit especially hard by the economic crisis: long-term jobseekers aged over 30, and those aged between [25 and 30] who do not benefit from the Youth Guarantee.

Equal treatment

The Council took stock of the state of play as regards the equal treatment directive (13877/1/15 REV 1).

– ***Work under the Luxembourg presidency***

The working party on Social Questions continued its examination of the text, focusing on the provisions concerning access to goods and services for persons with disabilities, and on the compatibility between these provisions and the United Nations convention on the rights of persons with disabilities (UNCRPD).

The presidency's drafting suggestions were supported in general by the Commission and broadly welcomed by delegations as a step in the right direction.

Strategic engagement for gender equality 2016-2019

The Council held an exchange of views on the Commission's strategic engagement for gender equality (14746/15).

A large number of member states stressed that a formal Strategy endorsed by the Commission was needed and expressed their disappointment in having received an informal working document instead.

Many member states felt that a new strategy covering the period 2016-2019 was essential for the promotion for gender equality and as a benchmark and guiding framework for national policies.

However, as regards the substance of the Commission's strategic engagement, member states generally supported the five priorities identified in the document:

– equal economic independence for women and men;

– equal pay for work of equal value;

– equality in decision-making;

– dignity, integrity and ending gender-based violence; and promoting gender equality beyond the EU.

The Strategic engagement defines the objectives across these five priority areas towards which the Commission will continue to work. It identifies key actions to be implemented in the five priority areas over the next years, with clear timelines. It also defines indicators for targets and monitoring. In addition, it emphasises the need to integrate a gender equality perspective into all EU policies as well as into EU funding programmes.

European semester 2016

The Council held an exchange of views on the European Semester.

The 2016 European Semester opened with the Commission's presentation, on 26 November, of a package containing the annual growth survey, the joint employment report and the alert mechanism report, and also the draft euro area recommendation.

Ministers pointed out that strengthening the recovery and fostering convergence can be built on the three following economic and social policy priority areas: re-launching investment, pursuing structural reforms and responsible fiscal policies.

They welcomed the fact that this year the employment and social dimensions of the alert mechanism report are strengthened through out the economic package.

The annual growth survey for 2016 maintains and updates the existing priorities, taking account of the progress made and new challenges. This year’s priorities are re-launching investment, pursuing structural reforms to modernise our economies and responsible fiscal policies. This year’s package places a strong emphasis on social and employment performance and the importance of social investment.

The joint employment report analyses the employment and social situation in the EU and the policies implemented to address it. The report notes that the employment and social situation is gradually improving but that differences between member states persist.

The alert mechanism report marks the beginning of the macroeconomic imbalance procedure. Since imbalances may hinder the performance of national economies, the euro area or the European Union as a whole, this report aims to identify the member states that warrant in-depth reviews to determine whether or not they are affected by imbalances.

In this context, the EPSCO Council also approved the employment and social aspects of the draft recommendation on the euro area. The recommendation will be adopted next year, after the economic aspects have been approved by the ECOFIN Council and it has been endorsed by the European Council.

Equality between women and men in the field of decision-making

The Council adopted conclusions on equality between women and men in the field of decision-making (14325/15).

These conclusions are part of the implementation of the Beijing platform for action which aims to empower women to take action.

They are based on a report prepared by the European institute for gender equality in the area of decision-making.

With the aim of monitoring the implementation of the 12 critical areas for action identified in the Beijing platform for action, successive presidencies have worked on the collection and analysis of data and drawn up indicators for certain critical areas of concern.

Social economy

The Council adopted conclusions on the promotion of the social economy as a key driver of economic and social development in Europe (13766/15).

The social economy is an important pillar, notably in terms of employment and social cohesion across Europe. It is a sector which has weathered the economic crisis better than others.

The social economy combines sustainable economic activities with positive social impact, while matching goods and services to needs. It contributes to several key EU objectives, such as the achievement of smart, sustainable and inclusive growth, high-quality employment, social cohesion, social innovation, local and regional development and environmental protection.

Social governance

The Council adopted conclusions on social governance for an inclusive Europe (14129/15).

The starting point for the conclusions was the five Presidents' report, which primarily concerns the consolidation of the economic and monetary union.

The conclusions also form part of the vision for a 'social triple-A rating' for Europe declared by the President of the European Commission.

Any other business

(a) Legislative proposals: The presidency informed the Council about the following (current) legislative proposals: regulation on a European Network of Employment Services, workers' access to mobility services and the further integration of labour markets (EURES); decision on a European Platform to enhance cooperation in the prevention and deterrence of undeclared work;

The Commission informed the Council about the European accessibility act.

(b) The Commission informed the Council about the European pact for youth launched at the enterprise 2020 summit which took place in Brussels on 16 and 17 November 2015.

(c) The Commission informed the Council about the list of measures to promote the equal treatment of lesbian, gay, bisexual and transgender people.

(d) The presidency informed the Council about the conferences/initiatives organised during its mandate.

(e) The Netherlands delegation informed the Council about the work programme of the incoming presidency.

HEALTH

EU strategy on reduction of alcohol-related harm

The Council adopted the following conclusions on "An EU strategy on the reduction of alcohol-related harm" (15050/15):

"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, and that Union action which is to complement national policies shall be directed towards improving public health, preventing illness and disease, and obviating sources of danger to physical and mental health. Such action shall also cover the fight against the major health scourges, by in particular promoting research into their causes and their prevention, as well as health information and education;

The Union shall encourage cooperation between the Member States in the field of public health and, if necessary, support their action. The Union and the Member States shall foster cooperation with third countries and competent international organisations. Union action shall fully respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of the resources assigned to them;

2. RECALLS that harmful use of alcohol has been recognised as an important risk factor set out in the communication from the Commission on the health strategy of the European Community[1] and that actions to reduce alcohol-related harm have been financed from the second and third Union Health Programmes[2];

[1] 8756/00.

[2] Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13); Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.

3. RECALLS the Council Recommendation of 2001 on the drinking of alcohol by young people[1], which invited the Commission, in cooperation with Member States, to make full use of all Community policies to address the matters covered in the recommendation, inter alia, the development at national and European level of comprehensive health promotion policies addressing alcohol;

4. RECALLS the EU Strategy to support Member States in reducing alcohol related harm (2006 - 2012)[2] as well as the Council Conclusions of 2001[3], 2004[4] and 2006[5,] inviting the Commission to put forward a comprehensive strategy aimed at reducing alcohol-related harm, the setting up of the Committee on National Alcohol Policy and Action (CNAPA) to support the implementation of such a strategy, as well as the Council Conclusions of 2009[6] inviting the Commission to define priorities for the next phase of the Commission's work on alcohol and health after the end of the first EU Alcohol Strategy in 2012;

5. WELCOMES the European Parliament Resolution on Alcohol Strategy of 29 April 2015 calling for a new EU Alcohol Strategy (2016-2022)[7], reiterating the importance of a strong political commitment from the Commission, Parliament, the Council and the Member States to increase efforts to prevent alcohol-related harm;

6. WELCOMES the WHO Global Strategy to reduce harmful use of alcohol[8] and the WHO European action plan to reduce the harmful use of alcohol 2012–2020[9];

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1 Council Recommendation 2001/458/EC of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents, (OJ L 161, 16.6.2001, p. 38).

2 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions of 24 October 2006, An EU strategy to support Member States in reducing alcohol related harm, COM (2006) 625 final.

3 Council Conclusions of 5 June 2001, OJ C 175, 20.6.2001, p. 2.

4 Council Conclusions of 2 June 2004 on alcohol and young people, 9507/04 (Presse 163).

5 Council Conclusions of 30 November 2006, EU strategy to reduce alcohol-related harm, 15258/06.

6 Council Conclusions on alcohol and health of 1 December 2009, OJ C 302, 12.12.2009, p. 15.

7 European Parliament resolution of 29 April 2015 on Alcohol Strategy (2015/2543(RSP)).

8 Resolution WHA63.13, page 27.

9 Resolution EUR/RC61/R4.

7. NOTES WITH CONCERN that, according to the WHO's Global Status Report on alcohol and health[1], harmful use of alcohol is among the world's leading risk factors for disease and disability, and that the European Union is the region with the highest alcohol consumption in the world with an average adult (aged 15+ years) alcohol consumption of 10.1 litres of pure alcohol in 2012[2];

8. NOTES WITH CONCERN that, according to the report of the Organisation for Economic Cooperation and Development (OECD) on Tackling Harmful Alcohol Use - Economics and Public Health Policy[3], regular and heavy drinking is on the rise in some Member States, and there is general concern at the alarming increase in alcohol consumption among young people (minors and young adults) and women in many Member States, and that alcohol abuse not only has a negative impact on the health of individuals, but also on society at large;

9. STRESSES that reducing the burden of alcohol-related avoidable death, chronic diseases and injuries, violence, health inequalities and other social consequences to third parties, as well as risky drinking behaviour in particular among young people, has become a common concern and that cooperation and coordination at EU level would be of added value;

10. STRESSES that prevention of alcohol-related harm represents a necessary investment, which is beneficial for the economy as it allows economic losses and healthcare expenditure to be limited in the long term, inter alia by decreasing the burden of chronic diseases, including cancer, and workforce productivity to be raised;

11. STRESSES also that reduction of harmful use of alcohol also has a positive effect on public security and road safety, in particular on the reduction of road deaths and injuries;

12. NOTES that the reduction of alcohol-related harm requires actions across a range of policy areas and involving many sectors across society, at both national and EU level;

13. REITERATES the call for an EU strategy on the reduction of alcohol-related harm expressed by a large number of ministers at the informal meeting of health ministers on 21 April 2015 as well as at the EPSCO Council on 19 June 2015, and underlines the fact that such an EU strategy can further support and complement national public health policies.

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1 WHO 2014, p. 46, p. 31.

2 Health at a Glance: Europe 2014 (joint publication of the OECD and the European Commission), December 2014.

3 Tackling Harmful Alcohol Use - Economics and Public Health Policy, May 2015.

INVITES THE MEMBER STATES TO:

14. CONTINUE to promote a multi-sectoral approach as regards the reduction of alcohol-related harm at national and EU level and strengthen or develop, as appropriate, comprehensive national strategies or action plans tailored to specific local and regional traditions;

15. ADOPT appropriate measures to address the protection of young people from harmful use of alcohol, notably in the field of the legal drinking age and marketing exposure and CONTINUE to support information and education on the harmful use of alcohol and particularly risky drinking behaviour.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

16. STRENGTHEN cooperation on identification of effective measures and best practices aimed at minimising health and social impacts as well as health inequalities stemming from of harmful use of alcohol, focusing particularly on prevention of risky drinking behaviour among young people, on people who consume alcohol at harmful levels or with harmful drinking patterns, on alcohol consumption during pregnancy and on driving while under the influence of alcohol;

17. CONTINUE to support the work of CNAPA, while taking into account the results of the implementation report on the first EU Alcohol Strategy[1] as well as the involvement of stakeholders at national and European level to reduce alcohol-related harm;

18. RECOGNISE the need to continue gathering information at EU level on the implementation of alcohol-related national legislation, respecting national competences as well as regional and local social and cultural traditions;

19. CONSIDER, in particular in the light of the report to be adopted by the Commission in accordance with Article 16(4) of Regulation (EU) No 1169/2011 on the provision of food information to consumers[2], the possibility of introduction of mandatory labelling of ingredients and nutrition declaration, in particular of the energy value, of alcoholic beverages.

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1 European Commission, Directorate-General for Health & Consumers, First progress report on the implementation of the EU Alcohol Strategy, September 2009.

2 OJ L 304, 22.11.2011, p. 18.

INVITES THE COMMISSION TO:

20. CONTINUE its support to Member States in their efforts to reduce alcohol-related harm, while fully respecting the principles of subsidiarity and proportionality;

21. ADOPT by the end of 2016, while fully respecting Member States' competences, a comprehensive EU strategy dedicated to the reduction of alcohol-related harm and comprising actions across EU policies in order to tackle health, social and economic consequences of the harmful use of alcohol. This dedicated EU strategy should focus on initiatives on the reduction of alcohol-related harm with a cross-border dimension and an EU added value as a follow-up to the first EU Alcohol Strategy (2006 - 2012) and should take into account the work carried out by CNAPA as well as work done under the WHO Global Strategy on Alcohol and the WHO European action plan to reduce the harmful use of alcohol 2012–2020;

22. REPORT to the Council on the outcome of its work and progress made in the field of reducing alcohol-related harm."

Personalised medicine for patients

The Council adopted the following conclusions on "Personalised medicine for patients" (15054/15):

"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, and that Union action, which is to complement national policies shall be directed towards improving public health. The Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action. Union action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, including allocation of the resources assigned to them;

2. RECALLS the Council conclusions on common values and principles in European Union health systems adopted on 2 July 2006[1], which define a set of operating principles shared across the European Union, especially regarding patient involvement and quality and safety of care, and which emphasise in particular that all European Union health systems aim to be patient-centred;

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF.

3. RECALLS the Council conclusions on innovation in the medical device sector adopted on 6 June 2011[1], which recognise that innovative medical devices could improve health and quality of life for patients and could contribute to addressing the sustainability of healthcare systems, and that innovation should be increasingly patient-centred;

4. RECALLS the Council recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02) and the incentives offered by Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products which are also used to encourage the development and authorisation of medicinal products for small populations;

5. RECALLS the Council conclusions on the reflection process on modern, responsive and sustainable health systems adopted on 10 December 2013[2], the Council conclusions on the economic crisis and healthcare adopted on 20 June 2014[3], as well as the Council conclusions on innovation for the benefit of patients adopted on 1 December 20144, which, while stressing the need to fully respect areas of Member States competence, advocate the need for cooperation on strategies to effectively manage expenditure on pharmaceuticals and medical devices, while ensuring equitable access to effective medicines within sustainable national healthcare systems; the Council conclusions on innovation for the benefit of patients have been followed-up by work in the Working Party on Public Health at Senior Level, including possible topics to serve as a basis for future discussions[5],

6. TAKES NOTE of the European Commission Staff Working Document on the use of '-omics' technologies in the development of personalised medicine[6], which highlights the potential and issues in the development of personalised medicine and concludes that the development of personalised medicine offers through the use of '-omics' technologies new opportunities for the treatment of patients in the European Union. It proposes that through this approach, healthcare providers may be able to offer better-targeted treatment, avoid medical errors and reduce adverse reactions to medicinal products. It also identifies several challenges to the implementation and uptake of personalised medicine in health systems;

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1 OJ C 202, 8.7.2011, p. 7.
2 OJ C 376, 21.12.2013, p. 3.
3 OJ C 217, 10.7.2014, p. 2.
4 OJ C 438/12, 6.12.2014.
5 9869/15 (Innovation for the benefit of patients: Follow-up to the Council's conclusions) 11039/1/15 REV1 (Outcome of proceedings of the Working Party on Public Health at Senior Level on 15 July 2015).
6 European Commission Staff Working Document, October 2013.

7. TAKES NOTE of the World Health Organisation (WHO) 2013 Priority Medicines Report[1], that discusses the role and the current limitations of personalised medicine, called ‘stratified medicine’ in the context of the report, and recommends investments to further strengthen research in and knowledge of stratified medicine and pharmacogenomics;

8. NOTES that there is no commonly agreed definition of the term “personalised medicine”. However, it is widely understood that personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs;

9. NOTES that, as DNA sequencing technologies, and other advanced ‘-omics’ technologies for the identification of multiple biomarkers are developing rapidly, there is the expectation that these developments could make it possible to use detailed risk profiling as an additional tool for targeted interventions, aiming at and potentially improving health outcomes and over time allowing for a more cost-efficient use of healthcare;

10. NOTES that, with the development of personalised medicine, individuals and health systems face new challenges, including balancing its risks and benefits while also considering its ethical, financial, social and legal implications, particularly regarding pricing and reimbursement, data protection and public interest in processing personal data;

11. NOTES that the development and implementation of personalised medicine goes hand-in-hand with the development of relevant diagnostics;

12. NOTES WITH CONCERN that not all patients have access to innovative methods of better-targeted prevention, diagnosis and treatments and that a significant challenge for Member States consists in promoting appropriate uptake in healthcare systems, in order to ensure integration into clinical practice in line with the principles of solidarity and universal and equal access to high quality of care, while fully respecting Member States competences, and ensuring the sustainability of their national health systems;

[1] http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf.

13. NOTES that personalised medicine is becoming a reality in research, particularly following the support of the Seventh Framework Programme for research, technological development and demonstration activities, which dedicated over EUR 1 billion to underpin personalised medicine for the period 2007-2013[1]. Funding research for personalised medicine will continue through the Framework Programme for Research and Innovation, Horizon 2020[2], including through actions carried out under the Innovative Medicines Initiative (IMI)[3];

14. WELCOMES the high-level conference of 8 July 2015 "Making Access to Personalised Medicine a Reality for Patients", which addressed obstacles to the integration of personalised medicine into European Union healthcare systems, identified best practices and their added value, and outlined the potential benefits of personalised medicine for public health and its impact on policy-making in the European Union. Involving public health decision-makers, regulators, payers and patients, the conference also underlined the need to define a patient-centred approach to personalised medicine at European Union level, as well as a comprehensive approach integrating the different phases along the life cycle of personalised medicine products in such a way as to facilitate its integration into clinical practice.

INVITES THE MEMBER STATES TO:

15. SUPPORT access, as appropriate, according to national provisions, to clinically effective and financially sustainable personalised medicine by developing patient-centred policies including, as appropriate, patient empowerment and the integration of patient perspectives in the development of regulation processes, in cooperation with patient organisations and other relevant stakeholders;

16. USE genomics information with a view to integrating advances in human genomics into public health research, policy and programs, in compliance with existing national provisions concerning personal data and genomics;

17. DEVELOP OR STRENGTHEN, if necessary, public health communication strategies, based on available, objective, balanced and non-promotional data to increase public awareness as regards both the benefits and risks of personalised medicine, as well as the citizens' role and rights, thus supporting appropriate access to innovative diagnostic methods and better-targeted treatment;

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1 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:i23022
For example the project PerMed (www.permed2020.eu).

2 http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf.

3 http://www.imi.europa.eu/.

18. PUT in place information and awareness strategies for patients, based on available, objective, balanced and non-promotional data, in order to improve health literacy and access to reliable, relevant and understandable information on existing treatment options, including expected benefits and risks, thus enabling patients to actively cooperate with healthcare professionals in choosing the most appropriate treatment strategies;

19. PROVIDE education, training and continuing professional development for health professionals in order to equip them with the necessary knowledge, skills and competences to make the most of the benefits that personalised medicine brings to patients and healthcare systems;

20. FOSTER cooperation in the collection, sharing, management and appropriate standardisation of data necessary for effective research into, and development and application of personalised medicine, in compliance with data protection legislation;

21. PROMOTE cross-disciplinary interaction, notably between specialists in genetics, in using statistical methodologies, bio- and health informatics and epidemiology and among health professionals, in order to ensure better understanding of the available data, more efficient integration and interpretation of information from multiple sources and appropriate decision-making on treatment options;

22. DEVELOP OR ADJUST, where necessary, procedures aiming to evaluate the impact of personalised medicine, in particular health technology assessment (HTA) procedures, to the specific nature of personalised medicine, taking into account, inter alia, added value from the patients perspective as well as enhanced cooperation and exchange of best practices, while fully respecting Member States competences;

23. RECOGNISE the potential of clinical and population-based biobanks for accelerating the discovery and development of new medicinal products; support the standardisation and networking of biobanks to combine and share resources, in compliance with data protection legislation;

24. CONSIDER exchange of information and best practices within the existing fora, which could support both appropriate access for patients to personalised medicines, as well as the sustainability of health systems;

25. CONSIDER developing long-term, patient-centred, strategic approaches on how to meet, with a public health perspective, the challenges associated with access to personalised medicine, while ensuring the sustainability of national health systems and fully respecting Member States competences;

26. EXCHANGE best practices in the field of personalised medicine and facilitate its appropriate use in health care practice.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

27. CONTINUE voluntary joint work, including the development of guidance and the definition of criteria, to support HTA on personalised medicine in accordance with the HTA strategy[1], while fully respecting Member States competences;

28. FOSTER enhanced cooperation between Member States within the HTA Network established in accordance with the Directive on the application of patients' rights in cross-border healthcare and HTA bodies under the future Joint Action;

29. PROMOTE the interoperability of electronic health records to facilitate their use for public health and research, through the eHealth Network established in accordance with the Directive on the application of patients' rights in cross-border healthcare, taking advantage of the support from the Connecting Europe Facility[2];

30. DEVELOP common principles on data collection based on standards and a sound legal framework and enabling the processing of patient data and the availability of comparable data at European Union level, allowing secondary use and analysis of data on a larger scale in compliance with data protection legislation, while fully respecting Member States competences;

31. ENCOURAGE early dialogue and provision of parallel scientific advice between innovators, regulators and HTA bodies, taking into account, as appropriate, input from patients, healthcare professionals and payers, to support evidence generation and regulatory authorisation, while fully respecting Member States competences;

32. ENCOURAGE dialogue with Member States' authorities and stakeholders to facilitate step-by-step implementation of the public health genomics approach both at European Union and national level on the basis of past European Union initiatives, such as the European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies – Public Health Genomics European Network[3], and facilitate ongoing European Union initiatives such as the position paper on Public Health Genomics in Cancer, to be developed under the Joint Action on Comprehensive Cancer Control with the support of the Commission expert groups on cancer control and on rare diseases;

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1 http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf.
2 http://ec.europa.eu/digital-agenda/en/connecting-europe-facility.
3 http://www.phgen.eu/typo3/fileadmin/downloads/QA_Report.pdf .

33. TAKE personalised medicine into account in the broader context of the future framework for sustainable European Union collaboration on patient safety and quality of care, requested in the Council conclusions on patient safety and quality of care of 1 December 2014;

34. CONTINUE the work of the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), which analyses issues related to the implementation of European Union pharmaceutical legislation with the aim of identifying ways to maximise effective use of existing European Union regulatory tools and further improve safe and timely access of medicines for patients, including innovative medicinal products; continue, within the STAMP expert group, to monitor progress on the adaptive pathway pilot project undertaken by the European Medicines Agency and its potential to allow early authorisation of a medicine for use in a well-defined patient population with a high level of medical need.

INVITES THE COMMISSION TO:

35. EXAMINE, based on a study under the Third Health Programme (2014-2020), how to realise the potential of Big Data, which is used in personalised medicine, in contributing to innovative, efficient and sustainable health systems, respecting the right to protection of personal data. This study should also consider ethical, legal and social aspects;

36. FACILITATE cooperation and PROMOTE exchange of best practices on education training and continuing professional development of health professionals in the field of personalised medicine;

37. PROMOTE the possibilities offered by the European Reference Networks within the framework of the Directive on patients' rights in cross-border healthcare, to help facilitate the implementation of translational cross-sectorial research, including, where appropriate, into personalised medicine for patients suffering from rare or low-prevalence diseases or complex diseases;

38. CONTINUE to promote the important contributions to personalised medicine from research carried out under the Framework Programme for Research and Innovation, Horizon 2020, including through actions carried out under the Innovative Medicines Initiative (IMI), in order to speed up the development of more effective preventive and diagnostic tools as well as better and safer medicines for patients."

Living with dementia: improving care policies and practices

The Council adopted the following conclusions on "Supporting people living with dementia: improving care policies and practices" (15055/15):

"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 must be ensured in the definition and implementation of all Union policies and activities, and that Union action, which is to complement national policies, is to be directed towards improving public health. The Union is to encourage cooperation between Member States in the area of public health and, if necessary, lend support to their actions and foster cooperation with competent international organisations. Union action must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, including allocation of the resources assigned to them;

2. NOTES WITH CONCERN that 47.5 million people worldwide are currently living with dementia, 58 % of which live in low- and middle-income countries. It is estimated that in the European Union 6.4 million people live with dementia[1];

3. RECALLS that dementia is one of the major causes of disability and dependency among older people worldwide and that it has a physical, psychological, social and economic impact on people living with dementia and on their families and caregivers, as well as on society[2];

4. RECALLS that while the majority of people with dementia are elderly, there are also a significant number of people with early onset dementia;

5. EMPHASISES patients' rights, particularly those related to human dignity, as laid down in the EU Charter of Fundamental Rights[3];

6. RECOGNISES that people can live well with dementia for a number of years, in particular if timely access, assessment, diagnosis and the right support are in place;

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1 WHO, Fact sheet No 362, March 2015, http://www.who.int/mediacentre/factsheets/fs362/en/; ALCOVE Joint Action report, Executive Summary, p. 29, http://www.alcove-project.eu/images/synthesis-report/ALCOVE_SYNTHESIS_REPORT_WP4.pdf.

2 WHO, Fact sheet No 362, March 2015.

3 See Chapter I on Dignity, available to download at http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

7. RECOGNISES the significant impact of dementia and of diseases linked to dementia on the financial sustainability of health and social security systems;

8. EMPHASISES the importance of promoting healthy lifestyles, including for brain health, throughout the life cycle, in order to increase healthy life years;

9. RECALLS that a better understanding of these conditions is required to achieve high health standards for an ageing society, which is one of the priorities of both the second and the current third Health Programme (2014-2020)[1];

10. RECALLS that numerous initiatives at EU level have also acknowledged dementia as a priority for action in the context of demographic change and reiterated the significant consequences of the increase in the number of people living with the disease[2];

11. RECALLS the Council Conclusions adopted on 16 December 2008 on public health strategies to combat neurodegenerative diseases associated with ageing, which called on the Commission to adopt an initiative in 2009 to combat these diseases[3];

12. RECALLS that the Commission proposed a new approach for making better use of Europe's public R&D funds through Joint Programming in key areas that include Alzheimer's disease. As a result, the Member-States led Joint Programming Initiative on Neurodegenerative Diseases (JPND) was launched in 2010 with the aim to better coordinate national research efforts in the field of neurodegenerative diseases and in particular Alzheimer's disease;

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1 Regulation (EU) No 282/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020); OJ 21.3.2014, L86/1

2 See overview on initiatives in the field of dementia – such as the ALCOVE Joint Action, the European Innovation Partnership on Active and Healthy Ageing, the European Pact for Mental Health and Well-Being, the European platform to facilitate proof-of-concept for prevention of Alzheimer's Disease (EPOC-AD) and the Innovative Medicines Initiative – contained in the staff working document on the implementation of the Commission Communication on a European initiative on Alzheimer's disease and other dementias, SWD(2014) 321 final of 16.10.2014.

3 http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104778.pdf.

13. RECALLS that the 7th Framework Programme for Research and Technological Development (2007-2013) spent more than EUR 576 million in funding on research on dementia and neurodegenerative diseases between 2007 and 2013; building on these results, Horizon 2020 (2014-2020), the new EU Framework for Research and Innovation – Horizon 2020 allows to further address dementia as a societal and health challenge, with already more than EUR 103 million invested in dementia-relevant research and innovation actions;

14. WELCOMES the Resolution of the European Parliament, adopted on 19 January 2011, on a European initiative on Alzheimer's disease and other dementias calling for dementia to be made an EU health priority and strongly urging Member States to develop dedicated national plans[1;]

15. RECALLS the first report of the World Health Organisation (WHO), 'Dementia: A Public Health Priority'[2], published in 2012, which provided information on and raised awareness of dementia and made it one of the priority conditions addressed in the WHO Mental Health Gap Action Programme[3], which aims to scale up care for mental, neurological and substance abuse disorders;

16. WELCOMES the Declaration of G8 Health Ministers on Dementia, adopted on 11 December 2013 at the G8 Summit, to foster innovation to identify a cure or a disease-modifying therapy for dementia by 2025 as well as strategic priority areas and to increase funding for research[4];

17. RECALLS the Italian Presidency Conference 'Dementia in Europe: a challenge for our common future', held in Rome on 14 November 2014[5], which provided an overview of initiatives on dementia in the EU, notably on prevention, treatment and elderly health promotion;

18. RECALLS the report of the Organisation for Economic Cooperation and Development (OECD) of 13 March 2015 entitled 'Better dementia care and a future cure require action today'[6], which reaffirmed the need for dementia to be made a political priority;

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1 2010/2084 (INI).
2 WHO, 'Dementia: a public health priority', 2012, available to download at http://www.who.int/mental_health/publications/dementia_report_2012/en/.
3 http://www.who.int/mental_health/mhgap/en/.
4 https://www.gov.uk/government/publications/g8-dementia-summit-agreements.
5 http://www.salute.gov.it/portale/ItaliaUE2014/dettaglioEvento.jsp?lingua=english&id=246.
6 http://www.oecd.org/newsroom/better-dementia-care-and-a-future-cure-require-action-today.htm.

19. WELCOMES the Call for Action signed by participants at the first WHO Ministerial Conference on Global Action Against Dementia in Geneva on 17 March 2015, which underlined governments' primary role and responsibility in responding to the challenge of dementia and emphasised the need for multi-sectoral and coordinated action at global and national level, aimed notably at advancing prevention, risk reduction, diagnosis and treatment of dementia[1];

20. STRESSES that in recent years dementia has become a high priority for more and more Member States, given the fact that development, adoption or implementation of national strategies, action plans or programmes addressing dementia are ongoing in the majority of the Member States; that Member States' initiatives already in place or under way are based on an integrated approach to the patient pathway which considers health and social issues;

21. WELCOMES the discussion at the informal meeting of EU Health Ministers on 24 September 2015 on fostering development and implementation of national strategies, action plans or programmes on dementia as well as on facilitating the exchange of best practices at EU level, taking into account WHO activities;

22. WELCOMES the second Joint Action on Dementia, to be launched in 2016.

INVITES THE MEMBER STATES TO:

23. ADDRESS dementia as a priority through cross-sectoral national strategies, action plans or programmes on dementia to provide appropriate treatment and assistance to people living with dementia, their families and caregivers, while ensuring the sustainability of health and social security systems.

24. CONTINUE to devote special attention to strengthening the coordination within Member States of relevant policies in the field of dementia, including reinforcing the role of primary care.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

25. RECOGNISE that continued collaboration across sectors among Member States and at EU level – taking into account WHO activities – will allow for a valuable contribution to improve the support of people living with dementia;

[1] http://www.who.int/mediacentre/news/releases/2015/action-on-dementia/en/#.

26. RECOGNISE the benefits of the empowerment of people living with dementia and encourage their inclusion in decision-making processes by strengthening their representation, particularly in initiatives, organisations and bodies in the field of dementia;

27. SUPPORT a gender-sensitive, individual-and research based approach in the elaboration of strategies, plans and programmes on dementia, taking account of groups with specific needs, the impact of cultural diversity on perceptions of dementia, as well as the expectations and rights of people living with dementia and their families and caregivers;

28. RECOGNISE the important role of families and caregivers, notably by ensuring their inclusion in decision making processes, and the need to protect their physical and mental wellbeing through adequate support.

29. ACKNOWLEDGE the important work of the Governmental Expert Group on Dementia in facilitating the sharing of experiences and good practices to support Member States in developing and implementing national strategies, plans or programmes on dementia;

30. SUPPORT work in the context of EU policy areas that might have an impact on dementia policy, notably the Working Party on Public Health at Senior Level as well as the Social Protection Committee (SPC)[1] and the Economic Policy Committee (EPC)[2] on health care and long-term care;

31. TAKE FORWARD, while fully respecting Member States' competences, discussions at EU level on the following issues:

a) the role of prevention and health promotion, risk reduction, early detection, timely diagnosis and post-diagnostic support in contributing to the reduction of the burden of dementia;

b) ways of ensuring that prevention, diagnosis, treatment and care is coordinated within countries, involving multidisciplinary expertise, and that it is delivered closer to home;

c) the added value of the exchange of best practices with a focus on key components and tools to ensure the quality of care of patients and the support of carers, in order to better assess the various approaches and practices in these areas;

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1 SPC Working Group on Ageing Issues, see http://ec.europa.eu/social/main.jsp?catId=758.

2 EPC Working Group on Ageing Populations and Sustainability, http://europa.eu/epc/working_groups/ageing_en.htm.

d) the promotion of the rights of people living with dementia, with a particular focus on the ethical dimension of dementia in order to ensure healthy ageing in dignity;

e) the use of the potential of eHealth and assistive technologies in improving support and care for people living with dementia;

f) the pooling of and access to existing knowledge about ongoing initiatives and the related evidence base as well as its integration into everyday practice in health and social care;

g) the need to promote the role and continuing education of health professionals to ensure the best possible support for people living with dementia and their families;

h) the promotion of dementia-friendly communities;

32. INTENSIFY research on dementia, building upon the result of EU funded projects such as EU Joint Programming Initiative on Neurodegenerative Disease (JPND), particularly on its risk factors and underlying pathophysiology, as well as translation of successful interventions on dementia management into clinical practice, also considering public-public, public-private and international partnerships;

33. BENEFIT from resources, models and tools successfully developed at EU level, such as those gathered by the European Innovation Partnership on Active and Healthy Ageing, the ALCOVE Joint Action and from the strategies developed for scaling-up good practices;

34. DEVELOP, where appropriate, in close cooperation with the Governmental Expert Group on Dementia, voluntary guidance based on a comprehensive and integrated perspective on dementia, taking into account the aspects of coordinated prevention and health promotion, timely diagnosis, post-diagnostic support, treatment and care, while respecting Member States' competences;

35. IDENTIFY and EXCHANGE, in close cooperation with the Governmental Expert Group on Dementia, good practices, notably as regards targeted prevention, including secondary prevention, health promotion, timely diagnosis, post-diagnostic support and therapy, research, training and further education of health professionals, as well as public information to combat stigma;

36. IMPROVE the quality of epidemiological information on dementia to facilitate the development of national strategies, actions plans or programmes as well as the exchange of good practices;

37. EMPHASISE the work of non-governmental organisations and voluntary work in the field of dementia aiming to contribute effectively to national strategies, action plans or programmes.

INVITES THE COMMISSION TO:

38. STRENGTHEN the cooperation of Member States in the Governmental Expert Group on Dementia to facilitate the sharing of information on policy frameworks and of good practices already in place, as well as to support countries in developing and implementing national strategies, plans and programmes on dementia;

39. FOSTER the ongoing cooperation with the WHO and the OECD on dementia, in close coordination with Member States."

Lessons learned from the Ebola outbreak

The Council adopted the following conclusions on "Lessons learned for Public Health from the Ebola outbreak in West Africa - Health Security in the European Union" (15056/15):

"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; that Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in those areas;

2. NOTES with concern that the Ebola Virus Disease (EVD) epidemic in West Africa has proved to be the largest epidemic of the disease on record, with more than 28,000 reported confirmed, probable and suspected cases and over 11,000 reported deaths[1], including about 500 of healthcare workers, since March 2014 and that, since its outbreak in December 2013, the epidemic has evolved into a public health, humanitarian and socio-economic crisis with an unprecedented impact on families and communities in affected countries;

[1] http://apps.who.int/ebola/ebola-situation-reports.

3. RECALLS the International Health Regulations (2005) [1] (IHR) adopted by the 58th World Health Assembly on 23 May 2005 which reinforced coordination among States Parties to the IHR as regards preparedness for and the response to a public health emergency of international concern;

4. NOTES the response to the outbreak of EVD by the Member States, the European Commission, the Health Security Committee (HSC), the European Centre for Disease Prevention and Control (ECDC) and the World Health Organisation (WHO);

5. WELCOMES the extensive response to the outbreak of EVD by the affected countries and the remarkable work by civil society and non-governmental organisations;

6. RECALLS that improving citizens' health security was a core aim of the second EU Health Programme (2008-2013)[2] and NOTES the overarching objective to 'protect Union citizens from serious cross-border health threats' as enshrined in the third EU Health Programme (2014-2020)[3];

7. RECALLS that Decision 1082/2013/EU on serious cross-border threats to health4 lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, with a view to coordinate and in order to complement national policies and ACKNOWLEDGES that the Decision enabled the Union to address the public health aspects of the Ebola outbreak while also reinforcing the interoperability of its preparedness and response capacities and that it provides a solid framework to tackle future public health crises similar to the Ebola outbreak;

8. WELCOMES that medical evacuation of Ebola patients to Europe was implemented through the collaboration between the WHO, the Commission services, Member States and the HSC;

9. UNDERLINES the importance of coordination of preparedness research at the European and global level and of the efforts made by the respective networks;

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1 http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410_eng.pdf.

2 Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13), OJ L 301, 20.11.2007, p. 3.

3 Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020), OJ L 86, 21.3.2014, p. 1.

4 Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013, OJ L 293, 5.11.2013, p.1.

10. UNDERLINES the important role of the HSC, established by Decision 1082/2013/EU, in supporting the exchange of information between the Member States and the Commission, as well as in facilitating the coordination of the preparedness and response planning to the outbreak and of risk and crisis communication;

11. WELCOMES that the EU and its Member States have invested €2 billion in addressing the Ebola crisis[1] and to ensure better preparation to tackle possible future outbreaks;

12. RECALLS that under "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)"[2] the EU has provided € 140 million on research on communicable diseases, such as Ebola;

13. RECALLS the Council Conclusions of 30 April 2009 on "Influenza A/H1N1 infection"[3] as well as the Council Conclusions of 12 October 2009 on "Pandemic (H1N1) 2009 – a strategic approach"[4] and the Council Conclusions of 13 September 2010 on "Lessons learned from the A/H1N1 pandemic – Health security in the European Union"[5], in which the Member States are invited to continue and to extend cooperation on preparation, monitoring, early warning and coordinated responses for all matters relating to public health emergencies;

14. SUPPORTS the ongoing efforts in reforming WHO's preparedness and response capacity as recommended in Resolution EBSS3.R1 on "Ebola: ending the current outbreak, strengthening global preparedness and ensuring the WHO's capacity to prepare for and respond to future large scale outbreaks and emergencies with public health consequences" adopted on 25 January 2015[6] and as a follow-up to the Final Report of the Ebola Interim Assessment Panel published on 7 July 2015[7];

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1 http://europa.eu/rapid/press-release_MEMO-15-5339_en.htm.

2 Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, OJ L 347, 20.12.2013, p. 104–173.

3 9392/09.

4 13635/09.

5 12665/10.

6 http://apps.who.int/gb/ebwha/pdf_files/EBSS3/EBSS3_R1-en.pdf?ua=1&ua=1.

7 http://who.int/csr/resources/publications/ebola/report-by-panel.pdf?ua=1.

15. WELCOMES the resolution of the European Parliament of 18 September 2014 on EU response to the Ebola outbreak[1] as well as its own-initiative report of 27 October 2015 on "the Ebola crisis: the long-term lessons and how to strengthen health systems in developing countries to prevent future crises"[2];

16. RECALLS the Ebola High Level Coordination meeting held in Brussels on 16 October 2014, co-organised by the Commission and the Italian Presidency of the Council of the European Union, where EU and EEA Ministers of Health reaffirmed joint efforts to reinforce preparedness and response activities to fight Ebola;

17. RECALLS the high level conference "Ebola: From Emergency to Recovery" held in Brussels on 3 March 2015[3] under the organisation of the European Union, which aimed to sustain the international mobilisation and to plan the next steps in the fight both against the current outbreak and the Ebola virus in general;

18. TAKES NOTE of the discussions on lessons learned from the Ebola epidemic that have taken place in various international fora since its outbreak and notably the G7 Health Ministers' Commitment "Lessons Learned from Ebola" adopted on 8 and 9 October 2015[4] underlining the need for better global public health crisis management and calling for greater cooperation in view of developing and maintaining core capacities for IHR implementation;

19. WELCOMES the Conference "Lessons learned for Public Health from the Ebola outbreak in West Africa" co-organized by the Commission and the Luxembourg Presidency of the Council of the European Union on 12 and 14 October 2015 in Luxembourg[5], which stressed the need for improved cross-sectoral cooperation as well as strengthened health security in the European Union in order to enhance and maintain the response and preparedness capacities of Member States in case of future outbreaks;

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1 2014/2842(RSP), http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2014-0026.

2 2014/2204(INI), http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2015-0281+0+DOC+XML+V0//EN&language=en.

3 http://europa.eu/rapid/press-release_IP-15-4521_en.htm.

4 http://www.bmg.bund.de/fileadmin/dateien/Downloads/G/G7-Ges.Minister_2015/G7_Health_Ministers_Declaration_AMR_and_EBOLA.pdf.

5 Conference report, http://ec.europa.eu/health/preparedness_response/events/ev_20151012_en.htm#c.

20. RECOGNISES that while preparedness and response planning as well as its implementation remain primarily a matter of national competence to be decided on by Member States, it is necessary to work together with a view to coordinate, where appropriate, national measures at EU level, in coherence with public health crises management at international level, notably within WHO and in line with Decision 1082/2013/EU on serious cross-border health threats.

INVITES MEMBER STATES TO:

21. MAINTAIN appropriate capacities, during and in between emergencies, in order to strengthen national preparedness and response activities, the international coordination and the implementation of lessons learned from previous incidents.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

22. IDENTIFY, ASSESS and TAKE FORWARD, as appropriate and while fully respecting Member States' competences, discussions of the following issues at EU level, notably within the HSC on the basis of the relevant provisions of Decision 1082/2013/EU and while taking into account relevant work at international level:

a) improvement of cross-sectoral coordination and collaboration in facing public health emergencies of international concern within the EU;

b) strengthening of risk-assessment and risk–management of serious cross-border threats to health;

c) exchange of good practices in the field of prevention and treatment, including protection and training of health care workers;

d) fostering of stronger involvement of relevant work and experiences of other stakeholders such as civil society and non-governmental organisations;

e) defining EU medical evacuation capacities in preparation for possible future emergencies;

f) strengthening of preparedness research, notably with regard to diagnostic methods, vaccines and therapeutic products development and improvement of coordination between the European and global research community;

g) the means and tools to deliver medical and public health assistance (emergency medical teams and experts) as part of the European Emergency Response Capacity under the Union Civil Protection Mechanism in collaboration with WHO and the Global Health Emergency Workforce, in accordance with Decision 1313/2013/EU on a Union Civil Protection Mechanism[1];

[1] OJ L 347, 20.12.2013, p. 924–947

h) strengthening of public health and health service expertise as regards the prevention of the spread, as well as control, management of serious cross-border health threats and treatment of related diseases e.g. by expert networks on screening and clinical case management as well as Europe-wide simulation exercises to test cross-sectoral coordination;

i) improving coherence of Members States risk and crises communication by consulting each other, with a view to coordinate, through the HSC and its communicators' network;

j) coherent implementation of core capacities in the EU and at global level, according to the IHR requirements, under WHO leadership, notably to build and strengthen resilient health systems, to promote the need for high quality surveillance and infrastructure and sharing of information;

k) strengthening of EU preparedness and response planning as part of enhanced global health security.

INVITES THE COMMISSION TO:

23. IDENTIFY opportunities to improve coordination mechanisms for future incidents that extend across different policy areas."

Any other business

– Medical devices and in vitro diagnostic medical devices.
The presidency informed ministers on the state of play of the discussions with the European Parliament on two draft regulations concerning medical devices and in vitro diagnostic medical devices (14215/15).

– Trans fatty acids.
The Commission presented its report on trans fatty acids.

– Conferences.
The presidency informed the Council about the outcome of conferences held during its term of office (14953/15).

– Work programme of the incoming presidency.
The Netherlands delegation informed ministers on its work programme in the field of health and consumer affairs as the incoming Presidency of the Council of the EU.

OTHER ITEMS APPROVED

COMMON SECURITY AND DEFENCE POLICY

EU border assistance mission in Libya - mandate extension

The Council extended the mandate of the European Union Integrated Border Management Assistance Mission in Libya (EUBAM Libya) until 21 May 2016. The Council decided that the financial reference amount for the period from 22 May 2014 to 21 May 2016 would be EUR 26 200 000.

Participation of Switzerland in the European Union CSDP mission in Mali

The Council authorised the opening of negotiations for the participation of Switzerland in the European Union CSDP mission in Mali (EUCAP Sahel Mali).

Participation of Switzerland in the EU advisory mission in Ukraine

The Council authorised the opening of negotiations for the participation of Switzerland in the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine).

EU appoints new European Union Special Representative for the Sahel

The Council appointed Angel Losada Fernandez as the EU Special Representative (EUSR) for the Sahel until 28 February 2017.

Budget of EU mission on regional maritime capacity building in the Horn of Africa

The Council decided that the financial reference amount for the EU mission on regional maritime capacity building in the Horn of Africa (EUCAP NESTOR) from 16 December 2015 to 12 December 2016 would be EUR 12 100 000.

FISHERIES

Trade measures - Supply of certain fishery products to EU processors

The Council adopted a regulation opening and providing for the management of autonomous EU tariff quotas for certain fishery products for the period 2016 to 2018 (*13502/15*).

The proposal's objective is to ensure a competitive provision of raw material to EU processors of fishery products who depend on imports. Autonomous tariff quotas provide member states' fish processing industries with an instrument to for further processing import unprocessed or semi-processed fish products at a favourable duty rate, mostly 0%, irrespective of their origin, up to a certain ceiling expressed in tonnes. The current quotas regime expire on 31 December 2015.

TRANSPARENCY- PUBLIC ACCESS TO DOCUMENTS

On 7 December 2015, the Council approved:

- the reply to confirmatory application No 22/c/01/15 (13946/15).