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OUTCOME OF THE COUNCIL MEETING

3474th Council meeting

Employment, Social Policy, Health and Consumer Affairs

Employment, Social Policy and Health

Luxembourg, 16 and 17 June 2016

Presidents **Lodewijk Asscher**
Vice Prime Minister and Minister for Social Affairs and Employment of the Netherlands
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- 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.

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ITEMS DEBATED

Employment and social policy

European Semester 2016

The Council held a policy debate on the employment and social policy aspects of the 2016 European Semester exercise, adopting relevant documents.

Ministers highlighted many important policy areas covered by the 2016 European Semester, such as active labour policies, labour market participation, poverty reduction and social inclusion.

They welcomed the reduced number of more focused country-specific recommendations and the enhanced cooperation between member states and the Commission, leading to shared analysis and better data.

Poverty reduction and improvement of the social situation is still to be achieved. Poverty is a complex phenomenon and requires the right mixture of policy measures. More efforts are needed to tackle social exclusion.

Changing economies and increasing global interdependency require adequate investment to achieve growth. Skilled labour is lacking in various sectors; labour shortage in growth sectors has to be addressed by encouraging cross-border activities too, without undermining social and labour standards.

Investment in education, training and skills are crucial for meeting the new demands of the labour market; active inclusion policies need to be comprehensive.

Actions at all levels need to include all relevant stakeholders, in particular the social partners in order to improve the implementation of the annual reform programmes.

– ***Labour market situation/ Unemployment***

The labour market situation has improved and is expected to improve further.

However, many challenges remain. The decrease in the unemployment rate is continuous but gradual, and still remains above pre-crisis levels.

Around one quarter of the EU population is considered to be at risk of poverty or social exclusion.

Employment and social matters should therefore remain at the forefront of member states' policy efforts and a key pillar of a strengthened EMU. Labour markets should become more inclusive, striking the right balance between flexibility and security.
Social security systems, which have been put to the test, need to build up their resilience.
The involvement of social partners in the reform design and implementation process will contribute to their success.

– ***Country-specific recommendations (CSRs)***

In the employment and social protection fields, the 2016 CSRs cover many areas: employment protection legislation and the framework for labour contracts; the tax burden on labour; unemployment benefits; active labour market policies; incentives to work, job creation, labour market participation; wages and wage-setting; childcare; health and long-term care; poverty reduction and social inclusion; education; skills and life-long learning.

This year, nearly half of the CSRs have an employment or social component, including a total of 114 specific recommendations touching upon the employment and social field. Compared to 2015, more emphasis was placed on the areas of skills, education and training, and active labour market policies. Less emphasis was placed on pensions, extending working lives and the employability of older workers, reflecting progress made by member states.

In the context of the policy debate, the Council endorsed the opinions of the Employment Committee (EMCO) and the Social Protection Committee (SPC) on the examination of the 2016 national reform programmes and the 2015 CSRs implementation.

Posting of workers

The Council took note of a progress report on a proposal on the posting of workers directive and of Commission information on the state of play for the yellow card procedure.

On 8 March 2016, the Commission submitted a proposal amending directive 96/71/EC. The new directive aims to ensure a level playing field for service providers while at the same time protecting the posted worker.

According to the Commission, the twenty-year-old directive no longer properly reflects developments since 1996 and the current situation in the labour markets, such as a considerably increased wage differentiation between sending and host countries.

On 10 May 2016, the eight-week period for the consultation of national parliaments ended. By this date, national parliaments of 11 member states sent reasoned opinions accounting for 22 votes. Thus, the threshold of one third of the votes required to trigger the 'yellow card' procedure has been reached. Consequently, the proposal must be reviewed by the Commission, which may decide to maintain, amend or withdraw it.

– ***Work in the Council working party***

The Working Party on Social Questions discussed the proposal at several meetings. A group of delegations raised concerns that the new proposal would undermine the internal market and drastically reduce the competitiveness of companies posting workers. This group preferred to suspend any work at technical level.

The majority of delegations however supported the Presidency's approach to continuing the work in order to finish ongoing business and to further clarify issues at technical level, such as the relationship between the proposal and the Rome I regulation, while fully respecting the national parliaments' reasoned opinions and the Commission's reflection period.

Accessibility for goods and services

The Council took note of a progress report on the proposal for a European accessibility Act, submitted by the Commission at the end of 2015.

The report reflects the discussions in the relevant working party of the Council, which clarified a large number of issues and undertook a thorough examination of the Commission's impact assessment. Particular attention was paid to the legal basis, the scope of the proposal and the question of which products, services and sectors should be covered.

The proposal covers a range of products and services accessible to persons with disabilities and functional limitations: electronic devices, websites, audiovisual media services, different transport services (e.g. ticketing machines and travel information) and banking services (e.g. websites, mobile device-based banking).

The aim of the proposal is to facilitate the implementation of the UN Convention on the rights of persons with disabilities. The Convention contains, inter alia, the obligation to increase the accessibility of goods and services. Most EU member states have already ratified the UN Convention and now need to undertake action to implement it. If this were done by each member state separately, it would lead to divergent legislations. This would fragment the internal market and lead to additional costs.

The proposed Act includes uniform accessibility criteria for selected goods and services for which the Commission deems the risk of divergence to be highest. These criteria are also meant to provide guidance for the implementation of other Union acts that include the obligation or possibility of improving accessibility, but do not specify what accessibility should mean.

Carcinogens or mutagens at work

The Council took note of a progress report on a revised directive protecting workers from the risks relating to exposure to carcinogens or mutagens at work.

This directive seeks to introduce stricter limit exposure values for a number of cancer-causing chemical agents as compared to those laid down by the 2004 directive.

The proposed revision concerns in particular annexes I and III to directive 2004/37/EC. In annex I, a provision is added on exposure to respirable crystalline silica dust generated by a work process.

With regard to annex III, while the current directive includes three carcinogenic agents (hardwood dust, benzene, and vinyl chloride monomer) and their limit values for occupational exposure, the proposal revises the limit value for two of these substances and includes new limit values for eleven substances.

In evaluating the latest scientific data, the Commission has been assisted by the Scientific Committee on occupational exposure limits.

A number of member states already have occupational limit values for substances included in the proposal. However, not all member states have set limit values and the existing values vary from one member state to another.

Equal treatment directive

The Council took note of a progress report on a directive implementing the principle of equal treatment between persons, irrespective of religion or belief, disability, age or sexual orientation.

The Dutch presidency has sought to clarify the interplay between this directive and the European accessibility Act. The latter contains detailed accessibility rules for certain products and services, which will benefit persons with disabilities. The equal treatment directive is a broader and more general instrument.

Certain member states have expressed doubts regarding subsidiarity, legal certainty and the division of competences of the Equal treatment directive.

The adoption of the directive would require unanimity in the Council.

Skills package

The Commission presented to the Council the new skills package adopted on 7 June.

The skills agenda is a new initiative following on from the numerous previous initiatives of the Commission in this area, such as the 2008 'New skills for new jobs' and the 2012 Commission communication on 'Rethinking education'.

The skills package contains a cross-cutting set of proposals covering areas such as skills development, the mutual recognition of qualifications and support for both vocational education and training and higher education, as well as ways of exploiting the full potential of the digital economy, as part of a European skills strategy aimed at promoting 'lifelong investment in people'.

Equality

The Council adopted the following conclusions on equality:

Response to the Commission's strategic engagement for gender equality

The Commission's strategy for equality between women and men 2010 - 2015 expired at the end of 2015. The Council and the European Parliament have invited the Commission to adopt a new strategy, and have stressed that it should have the same status as the previous one, meaning it should be officially adopted as a communication.

At the EPSCO Council on 7 December 2015, ministers held an exchange of views on the Commission's strategic engagement. Many ministers lamented the fact that no formal strategy had been adopted, as this implicitly downgraded the status of gender equality policy within the EU.

Nevertheless, 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.

Response to the Commission's list of actions to advance LGBTI equality

In December 2015, the Commission published a list of specific targeted actions to combat LGBTI discrimination in the EU in 2016-19. The actions have been defined in consultation with the EP, civil society and member states, and in the light of research carried out by the EU fundamental rights agency, information from relevant international bodies, and the Commission's own data.

Despite the evidence of widespread discrimination and harassment experienced by LGBTI persons, only limited action has been taken so far at EU level to address the problem.

Workplace discrimination on the grounds of sexual orientation is already prohibited by Council directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation.

Social dialogue

The Council adopted conclusions on social dialogue.

The new start for social dialogue was launched in March 2015. This was followed by a year-long round of discussions organised by the Commission departments and which involved the European social partners and a selection of national and sectoral social partners as well as several member states.

Combating poverty/social exclusion

The Council adopted conclusions on an integrated approach for combating poverty and social exclusion.

ILO work in fishing Convention

The Council took note of a progress report on a directive giving legal force to the EU-level sectoral social partner agreement concerning the implementation of the ILO's 2007 work in fishing Convention.

The Social Partner agreement aims to encourage the ratification of this ILO Convention. It is about launching the process of codifying and clarifying the EU legislative framework concerning working conditions in the fisheries sector by merging existing provisions with new provisions from the ILO Convention.

The main ambition is to create a level playing field for EU workers and employers once the Convention enters into force, giving fishermen decent working and living conditions on board fishing vessels.

Any other business

a) International dimension of employment and social policies

The Commission informed the Council about the international dimension of employment and social policies.

b) Follow-up to the Commission on the status of women

The Commission informed the Council about the work of the UN Commission on the status of women, with particular reference to measures to combat violence against women.

c) Migration compact

The Italian delegation informed the Council about the migration compact.

d) Work programme of the incoming Presidency

The Slovak delegation informed the Council about its work programme.

Health

Food products improvement

The Council adopted the following conclusions on food product improvement:

"THE COUNCIL OF THE EUROPEAN UNION

RECALLS

1. Article 168 of the Treaty on the Functioning of the European Union (TFEU)[1], which states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities and which provides that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, support their action.

   Article 26 TFEU, which states that the internal market shall comprise an area without internal frontiers in which the free movement of goods is ensured.

2. The Council conclusions of 6 December 2007 on the Commission White Paper on a strategy for Europe on nutrition, overweight and obesity-related health issues[2], which, in the context of an integrated approach to tackle nutritional challenges, called upon Member States to support activities aimed at reformulating foods to reduce levels of salt, saturated fat, trans-fatty acids, added sugar and energy density, given the role these elements play in the development of non-communicable diseases, overweight and obesity.

3. The Council conclusions of 8 June 2010 on action to reduce population salt intake for better health[3], which called upon Member States to strengthen or develop coordinated and sustainable national nutritional policies, including salt reduction programmes, to reduce salt consumption to an appropriate level.

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1 OJ C 326, 26.10.2012, p.47 (consolidated version).
2 15612/07.
3 OJ C 305, 11.11.2010, p. 3.

4. The EU Framework for National Initiatives on Selected Nutrients[4], established in 2011 following the positive results of the EU Framework for National Salt Initiatives[5], to which were added, in 2012, Annex I on saturated fat[6] and, in 2015, Annex II on added sugars[7], providing political guidance for action.

5. The Council conclusions of 20 June 2014 on nutrition and physical activity[8], and the Action Plan on Childhood Obesity, recognising the beneficial impact of disease prevention on both citizens and health systems and the importance of healthy diet in reducing the risk of chronic conditions and non-communicable diseases, which invited the Member States to continue to make healthy diet a top priority, thus contributing to better health and quality of life of EU citizens and the sustainability of the health systems.

6. EU Member States' support for the World Health Organisation's (WHO) global action plan for the prevention and control of NCDs 2013-2020, of 27 May 2013[9], which called for a reduction in the preventable and avoidable burden of morbidity, mortality and disability due to non-communicable diseases by means of multisectoral collaboration and cooperation at national, regional and global levels, so that populations reach the highest attainable standards of health and productivity at every age and those diseases are no longer a barrier to well-being or socioeconomic development.

7. The conclusions of the *report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population* [10].

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4 http://ec.europa.eu/health/nutrition_physical_activity/docs/euframework_national_nutrients_en.pdf

5 http://ec.europa.eu/health/archive/ph_determinants/life_style/nutrition/documents/salt_initiative.pdf

6 http://ec.europa.eu/health/nutrition_physical_activity/docs/satured_fat_eufnisn_en.pdf

7 http://ec.europa.eu/health/nutrition_physical_activity/docs/added_sugars_en.pdf

8 OJ C 213, 8.7.2014, p. 1.

9 http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf

10 http://ec.europa.eu/food/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

8. The Conference on Food Product Improvement, organised by the Presidency, in Amsterdam, on 22 and 23 February 2016[11], where a *roadmap for action on food product improvement*[12], to develop more concerted action to move step by step towards a healthier product offer, was endorsed by the majority of the Member States and by Norway and Switzerland as well as by food business operators and health-related non-governmental organisations.

NOTES WITH CONCERN THAT

9. The prevalence of overweight, obesity and other diet-related non-communicable diseases in the European population is too high and is still rising. This has a negative impact on life expectancy, reducing Union citizens' quality of life and affecting society, for example by threatening the availability of a healthy and sustainable workforce and inducing high healthcare costs which may affect the sustainability of the healthcare systems. It thus also imposes an economic burden on the Union and its Member States.

10. In particular, the high prevalence and rise of overweight and obesity among children is a serious concern, calling for strong concerted action, as already addressed at the level of the Member States, the Union and the World Health Organisation (WHO)[13].

11. Nutrition plays an important role in this context, alongside other lifestyle-related matters: the diet of many Europeans contains too much salt, saturated fats, sugars and energy value, mostly through consumption of processed or prepared foods, whilst at the same time most people do not consume enough fruits, vegetables and wholegrain products. In some Member States, people are still exposed to high amounts of trans fatty acids.

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11 http://english.eu2016.nl/events/2016/02/22/thematic-conference-on-product-improvement

12 https://www.rijksoverheid.nl/documenten/formulieren/2016/02/22/roadmap-for-action-on-food-product-improvement

13 Non-exhaustive list: EU Strategy on Nutrition, Overweight and Obesity-Related Health Issues 2007; Political Declaration of the High-level Meeting of the General Assembly (of the United Nations) on the Prevention and Control of Non-communicable Diseases" of 2011; WHO European Food and Nutrition Action Plan 2015–2020; Vienna Declaration on Nutrition and Non-Communicable Diseases in the Context of Health 2020; EU Action Plan on Childhood Obesity 2014 – 2020.

RECOGNISES THAT

12. For people's diet to improve, the healthy choice should be the easy choice.

To achieve such an objective, a holistic approach is needed: physical and social environments that support and encourage healthy patterns of food consumption as well as objective nutrition information and public-health driven education are key for policies and actions at national and local level.

Food product improvement, by reducing among others the levels of salt, saturated fats, added sugars[14] and energy value, as well as improving the availability of small and/or reduced portion sizes[15], is an important tool to make the healthy choice easy. In general such reduction should not lead to an increase in energy value[16] and should not decrease the quality and safety of the products.

13. To reach the majority of the population, in particular children and vulnerable groups, more action is needed on mainstream products that are consumed by the majority of the European population on a daily basis.

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14 In the sense used in Annex II to the EU framework for national initiatives on selected nutrients (http://ec.europa.eu/health/nutrition_physical_activity/docs/added sugars_en.pdf) 'added sugars' refers to sucrose, fructose, glucose, starch hydrolysates (glucose syrup, high-fructose syrup) and other isolated sugar preparations used as such or added during food preparation and manufacturing, as well as sugars present in honey, syrups and fruit juices and fruit-juice concentrates.

15 A number of foods are packed (biscuits, chocolate bars, milk drinks, yogurts, nuts, salads, preserves, etc.) or sold (hamburgers, dishes in canteens, etc.) in portions designed to be consumed immediately or once open. There are no unified 'sizes' for such portions, but it is clear that the size chosen by the producer is a clear invitation to consumption, as people avoid wasting food. Smaller portions offer more flexibility for the consumer, as a second portion will only be eaten through an active decision.

16 However, even if the energy value remains unchanged, reductions of saturated fats or added sugars can be encouraged through an increase of recommended nutritional components that are not generally consumed in sufficient amounts (e.g. fibre, fruits and vegetables).

14. Accessible and affordable improved food products can contribute to the goal of decreasing health inequalities, as vulnerable groups, for whom it might be difficult to make healthy choices, could more easily opt for improved products as they become more widely available.

15. Governments have the responsibility for setting public health objectives, which should, subsequently, be achieved in cooperation with food business operators and other relevant stakeholders. Food business operators[17] throughout the food chain have a responsibility towards improving the products and meals they offer and, by doing so, contribute to making the healthy choice the easy choice. Guidelines on the composition of foods to be provided by public bodies (such as hospitals, schools and residences for elderly people or students), including through public procurement, can also play a major role in supporting these objectives.

16. The point of departure varies between Member States, some of which already have a history in food product improvement, for example by setting compositional criteria for products, criteria for school meals and other food provided via public procurement, – validating the proposals of food business operators – criteria relating to labelling or to the marketing of food products to children, and criteria for portion sizes.

17. Cultural differences in preferences and dietary patterns can partly determine the approach, the pace of reduction of salt, saturated fat, added sugars and the final results. Every approach should acknowledge those cultural differences and dietary patterns. Local and traditional foods, including geographical indications[18], intrinsically tied to a country's culture and heritage, could be subject to special consideration, taking into account the national situation, for example their contribution to the overall dietary intake.

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17 This includes, among others, manufacturers, retailers, caterers, bars, restaurants and other providers of food.

18 http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/

18. Salt, saturated fats and added sugars should be reduced in food gradually, to enable consumer acceptance of improved products. Food for infants and children deserves specific attention, to develop broad tastes, including for fruits and vegetables, and avoid early development of taste preference for high-sugar and high-salt foods.

19. Food is extensively traded across borders within the internal market; therefore, food product improvement calls for cross-border cooperation in order to be effective from the public health and industry points of view, thus ensuring a high level of consumer and health protection and better functioning of the internal market.

20. Small and medium-sized enterprises (SMEs) which would like to participate in food product improvement initiatives may lack the necessary resources or skills to work on food product improvement; raising awareness among SMEs and encouraging support and attention for SMEs through the voluntary sharing of knowledge and best practices is important in view of their market share.

21. The improvement of the composition of food products opens up great possibilities for innovation and business opportunities and can lead to a market advantage. Within companies, increased coherence between the development of improved food products and marketing investment is desirable and expected in order to promote the healthiest options in the portfolio of companies and make the healthy choice easy.

22. Including companies' nutrition and health activities specifically related to food product improvement in auditing initiatives concerning corporate social responsibility could be a valuable incentive.

23. Research provides the necessary information for a solid approach to food product improvement; in general, the necessary know-how for the first important steps in improvement is available, but such information could be better distributed and exploited.

24. Data on current consumption and product composition help to make it possible for actions to be targeted at the most relevant product groups. The transparency and accessibility of such data facilitate the adoption of good practices.

25. Regular, transparent, credible and independent monitoring of product composition is essential for insight into the market situation and into the results of actions undertaken.

26. Other factors, such as technological possibilities, food safety and sustainability goals, may influence results in food product improvement.

CALLS UPON THE MEMBER STATES TO

27. Have a national plan for food product improvement in place by the end of 2017, either as a new plan or integrated into an existing plan, in cooperation with the relevant stakeholders, to make the healthy choice easier for consumers by 2020, through an increased availability of food with lower levels of salt, saturated fats, added sugars, energy value and, where appropriate, through reduced portion sizes and to provide information on the nutritional composition of processed foods. Local and traditional foods, including geographical indications[19], intrinsically tied to a country's culture and heritage, could be subject to special consideration, taking into account the national situation, for example their contribution to the overall dietary intake.

28. Make full use of all existing structures and tools, including the online tools of the EU Health Policy Platform[20], for sharing experiences on new initiatives and actions, as well as best practices, aimed at promoting food product improvement.

[19] http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/

[20] http://ec.europa.eu/health/interest_groups/policy_platform/index_en.htm

CALLS UPON THE MEMBER STATES AND THE COMMISSION TO

29. Report regularly, at least every two years, on progress achieved in food product improvement initiatives, and share benchmarks, where available, best practices of implementation and results, within the framework of the High Level Group (HLG) on Nutrition and Physical Activity[21].

30. Integrate the multidimensionality of food product improvement by involving representatives responsible for the areas of health, agriculture, food, economy and distribution, innovation, research and the internal market in the actions undertaken.

31. Support technological and research projects in the field of food product improvement aimed at developing and applying sound and up-to-date scientific knowledge.

32. Raise awareness and facilitate involvement of SMEs, e.g. by supporting research projects aimed at improving food composition, disseminating information on food product improvement techniques and applying criteria relating to food product improvement to relevant structural funds, thus providing affordable solutions for SMEs when improving food products.

CALLS UPON THE COMMISSION TO

33. Assess existing benchmarks for the reduction of salt and saturated fats in the context of the EU Frameworks for National Salt Initiatives and National Initiatives on Selected Nutrients and support the development of new possible benchmarks within the context of the HLG within a clear timeframe.

[21] http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm

34. While respecting Member States' competence, continue to involve the stakeholders concerned at Union level, including food business operators, in the food product improvement process, by:

a) continuing to support coordination and cooperation between the HLG on Nutrition and Physical Activity and the EU Platform for Action on Diet, Physical Activity and Health[22], for more focused discussions and exchanges of information on food product improvement;

b) establishing working groups with experts from both Member States and stakeholders within the EU Platform for Action on Diet, Physical Activity and Health:

- to work on improving the methodology, quality and share the results of monitoring activities[23];
- to suggest possible criteria regarding salt, saturated fats, added sugars and, where appropriate, portion sizes for food categories throughout the food chain;
- to look for other possible ways to increase the availability of healthy choices, particularly by also increasing beneficial nutritional elements that are recommended to be consumed and in general are not sufficiently consumed.

c) supporting clear, transparent and flexible working procedures (e.g. exchange of information by electronic means and guidance for public-private cooperation) and making the progress achieved and results attained by the working groups publicly available, for example via the online EU Health Policy Platform, to optimise the work of the groups.

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22 http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm

23 For monitoring purposes the focus should be on total sugars instead of added sugars, since (currently) only total sugars can be analysed.

35. Continue to support the improvement of the scientific basis, monitoring and data collection and sharing at EU level regarding improved products, consumption and new production methods.

    Monitoring of progress to be outlined with the Joint Action on Nutrition and Physical Activity (JANPA) [24] coordinated by France and to be seen in the light of the work of ongoing activities of WHO Europe, the European Commission and the Joint Research Centre (JRC).

36. Invite the JRC to participate in the autonomous verification and monitoring of EU Platform commitments with regard to food product improvement, which should be measurable, comparable and monitored in a sound and transparent way.

37. Increase coordination and alignment of research activities and open research data to underpin the development of improved food products through the Joint Programming Initiative: Healthy Diet for a Healthy Life.

38. Where possible, closely coordinate all new activities with regard to food product improvement with existing groups and actions, such as the JANPA and the WHO European Salt Action Network (ESAN, coordinated by Switzerland).

39. Facilitate the exchange of best practices, in particular through the following actions:

    a) setting up special pages on food product improvement on the online multi-stakeholder EU Health Policy Platform, with links to existing databases where possible, where all stakeholders involved can share experiences, challenges, knowledge, showcase results, identify obstacles in the EU internal market and share possible solutions to these obstacles;

    b) updating all stakeholders on planned and implemented actions at the regular meetings of the HLG and the EU Platform for Action on Diet, Physical Activity and Health."

[24] http://www.janpa.eu/

Antimicrobial resistance

The Council adopted the following conclusions on "the next steps under a one health approach to combat antimicrobial resistance":

"The Council of the European Union

1. RECALLS the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine[1] and the reports of December 2005, April 2010 from the Commission to the Council on its implementation[2] and the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections[3] and the reports of November 2012 and June 2014 from the Commission to the Council on its implementation[4].

2. RECALLS the Council conclusions of 10 June 2008 on antimicrobial resistance (AMR)[5], the Council conclusions of 1 December 2009 on innovative incentives for effective antibiotics[6], the Council conclusions of 22 June 2012 on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a 'One Health' perspective[7] and the Council conclusions of 1 December 2014 on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance[8].

1 OJ L 34, 5.2.2002, p.13
2 5427/06 [COM(2005)684 final] and 8493/10 [COM(2010)141 final]
3 OJ C 151, 3.7.2009, p.1
4 COM(2012)0658 and COM(2014)0371
5 9637/08
6 OJ C 302, 12.12.2009, p. 10
7 OJ C 2011, 18.7.2012, p. 2
8 OJ C 438, 6.12.2014, p. 7

3. RECALLS the European Parliament Resolution of 12 May 2011 on antibiotic resistance[9], the European Parliament Resolution of 27 October 2011 on the public health threat of antimicrobial resistance[10], the European Parliament Resolution of 11 December 2012 on the Microbial Challenges – Rising Threats from AMR[11] and the European Parliament Resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance[12].

4. RECALLS the 2001 Community Strategy against AMR[13] and the European Commission Communication of 15 November 2011 on an action plan against the rising threats from Antimicrobial Resistance[14] and the outcome of the evaluation of the 5 years action plan of the European Commission.

5. WELCOMES the Global Action Plan (GAP) on Antimicrobial Resistance[15] developed by the World Health Organisation (WHO) with the contribution of the Food and Agricultural Organization (FAO) and the World Organization for Animal Health (OIE) and unanimously adopted in May 2015 by the 68th World Health Assembly, calling all Member States of the World Health Organization to put in place national action plans against AMR by mid-2017.

6. WELCOMES the Resolution on Antimicrobial Resistance adopted in June 2015 by the 39th Conference of the FAO and the Resolution combating Antimicrobial Resistance and promoting the prudent use of antimicrobial agents in animals in May 2015 at the World Assembly of Delegates of the OIE.

7. WELCOMES the Codex Alimentarius Commission[16] initiative with regard to the need to review and update standards, codes and guidelines related to AMR.

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9 P7_TA(2011)0238
10 P7_TA(2011)0473
11 2012/2041 (INI)
12 2014/2207(INI)
13 COM/2001/0333 final Volume I.
14 16939/11 [COM(2011)748]
15 http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_ACONF1Rev1-en.pdf?ua=1
16 CAC 39-CL2015/21

8. WELCOMES other international and regional initiatives such as the declaration by the G7 on Antimicrobial Resistance[17] and the decision to put antimicrobial resistance on the agenda of the G20.

9. RECALLS that regarding human health, the Union's action is defined by Article 168 of the Treaty on the Functioning of the European Union.

10. RECALLS that antimicrobial resistance is a cross-border health threat that cannot be sufficiently addressed by one Member State alone and cannot be confined to a geographical region or a Member State and hence needs intensive cooperation and coordination between Member States, as stated in the Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health[18].

11. RECALLS that in the veterinary sector a number of legislative and non-legislative measures have already been taken and are taken at EU level to coordinate and ensure a common EU approach reducing the risk of AMR. These measures include especially those set out in the Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[19], prohibiting the use of antibiotics as growth promoters, Commission Implementing Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria[20], Commission Decisions following referral procedures under Directive 2001/82/EC, resulting in modifications of marketing authorisations for products containing critically important antimicrobials in order to reflect specific measures against development of AMR and in the Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)[21].

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17 https://www.g7germany.de/Content/EN/Artikel/2015/06_en/g7-gipfel-dokumente_en.html
18 OJ L 293, 5.11.2013, p.1-15
19 OJ L268, 18.10.2003, p. 29
20 OJ L 303, 14.11.2013, p. 26
21 OJ C 299, 11.9.2015, p. 7

12. WELCOMES the ongoing work of the Organisation for Economic Co-operation and Development (OECD) and the World Bank on the economic impact of AMR.

13. EXPRESSES ITS CONCERN regarding the data provided by OECD, according to which, it is estimated that about 700 000 deaths may be caused globally each year by AMR. Compared to a world with no AMR, the economic impact associated with current rates of AMR may reach about 0.03% of GDP in 2020 in OECD countries, 0.07% in 2030 and 0.16% in 2050. This would result in cumulative losses of about USD 2.9 trillion by 2050[22].

14. ACKNOWLEDGES the Scientific Opinions and reports on antimicrobial resistance published by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).

15. RECOGNISES that due to the complexity of the problem, its cross-border dimension and the high economic burden, the impact of antimicrobial resistance goes beyond its severe consequences for human and animal health and has become a global public health concern that affects the whole of society and requires urgent and coordinated intersectoral action, where necessary based on the precautionary principle[23].

16. UNDERLINES that in order to stimulate the development of new antimicrobials, alternative therapies and (rapid) diagnostics, EU and global coordination and cooperation on research programmes and incentives are needed and RECOGNISES the work done by the Innovative Medicines Initiative (IMI) project DRIVE-AB (Driving reinvestment in research and development and responsible antibiotic use), the proposals of the Antimicrobial Resistance Review team[24] and the Joint Programming Initiative on Antimicrobial Resistance[25] among others.

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22 http://www.oecd.org/els/health-systems/Antimicrobial-Resistance-in-G7-Countries-and-Beyond.pdf ;
NB: in the quoted report the amount "trillion" means 10^{12}

23 Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2 February 2000).

24 Lead by J. O'Neill (http://amr-review.org/)

25 http://www.jpiamr.eu/

17. STRESSES that more cooperation between Member States and with the Commission and pharmaceutical industry is crucial regarding the reduced availability including possible withdrawals from the market of antimicrobials that may lead to shortages in antimicrobials and inadequate replacement therapy.

18. HIGHLIGHTS that to make progress in the fight against AMR, the new EU Action Plan should contain measurable (clearly defined quantitative or qualitative) goals, benchmarks and effective measures to achieve these goals.

19. HIGHLIGHTS that the success of the fight against antimicrobial resistance relies heavily on the commitment and willingness of governments to take actions to ensure the implementation of the initiatives under the One Health approach involving all relevant sectors and on the will of the EU Member States to cooperate within the EU and at an international level.

20. WELCOMES the EU Ministerial One Health Conference on AMR[26] held in Amsterdam on 9 and 10 February 2016, at which the political will to tackle the AMR problem, by means of a One Health approach was expressed, including among others, enhanced cooperation between the Member States through a EU One Health Network on AMR. The EU One Health Network will not be a new governance structure, but it will work through joint meetings of existing groups or bodies in the human health, food and veterinary field, such as the AMR working group and the Health Security Committee. The EU One Health Network will be used on a regular basis, to discuss AMR related issues from a one health perspective, i.a. the exchange of information between Member States about the progress made on the implementation of the National Action Plans against AMR and the development and implementation of the EU Action Plan.

26 http://english.eu2016.nl/events/2016/02/10/ministerial-conference-on-amr

21. CALLS UPON THE MEMBER STATES TO:

1. have in place before mid-2017 a national action plan against Antimicrobial Resistance, based on the One Health approach and in line with the objectives of the WHO Global Action Plan. The national action plan, adapted to the national situation, should:

a) ensure that measures and actions in the different domains take into account the public health concerns of AMR;

b) be developed and implemented in cooperation between all relevant ministries and the relevant stakeholders in the public and private sector;

c) include measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sector and antimicrobial resistance in all domains. These goals could be qualitative and/or quantitative and should be addressed through effective measures adapted to the Member States' national situations;

d) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in veterinary medicine, according to EU[27] and national guidelines, including actions to avoid the routine preventive use of veterinary antimicrobials and actions to restrict the use in animals of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);

[27] Commission Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)
http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

e) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in human medicine including actions to improve prescribing practices and prudent use of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);

f) include the mechanism for implementation of national action plans and monitoring of their progress, including the way to further strengthen surveillance and to improve the quality and comparability of the data reported to ECDC, EFSA and EMA on the use of antimicrobials and on resistance in humans, animals, the food chain and possibly the environment;

g) include the way enforcement of legislation relevant to AMR is organised and ensured in the Member State;

h) include education programmes, where appropriate, and targeted campaigns to raise awareness among consumers, animal keepers and relevant professionals;

2. within the EU One Health Network, present their national action plans and share best practices, discuss policy options, ways to better coordinate responses and keep each other updated on the progress made on the implementation of the action plans;

3. support dialogue with the pharmaceutical industry in order to keep existing effective antimicrobials used in human and veterinary medicine on the market, and explore alternative solutions to ensure availability of these antimicrobials on the market;

4. join or strengthen their commitment to the existing Joint Programming Initiative on AMR[28];

28 http://www.jpiamr.eu/

5. promote and facilitate the implementation of measures to prevent infections in animals such as the use of vaccines and biosecurity measures in order to reduce infection pressure and therefore the need to use antibiotics;

6. promote the use of diagnostic tools including rapid tests and their uptake in the human and veterinary sector as means to improve the prescription of antimicrobials.

22. CALLS UPON THE MEMBER STATES AND THE COMMISSION TO:

1. develop together, while respecting Member States competencies, a new and comprehensive EU Action Plan on Antimicrobial Resistance based on the One Health approach, taking into account the evaluation of the current Action Plan, the discussion at the EU Ministerial One Health Conference on AMR of 10 February 2016 and the WHO Global Action Plan. The new EU Action Plan should include the following measures and measurable[29] goals:

a) measures to prevent infections and to ensure prudent use of antimicrobials in human and veterinary medicine;

b) measures to combat illegal practices related to the trade and use of antimicrobials, in human and veterinary medicine;

c) align surveillance on AMR in humans, food, animals and environment at EU level;

d) decrease, over the period of the new EU Action Plan, antimicrobial resistance in humans, animals and in the environment in the EU;

29 See paragraph 18.

e) decrease, over the period of the new EU Action Plan, the differences between Member States, in use of antimicrobials in both human and animal health, whereas Member States with a relatively low use should also try to further pursue prudent use of antimicrobials;

f) decrease, over the period of the new EU Action Plan, healthcare associated infections in the EU;

g) develop indicators to assess the progress made on addressing AMR and on the implementation of the EU Action Plan.

2. strengthen coordination and cooperation between Member States, between Member States and the Commission, and between human, food, veterinary, environmental, research and other relevant sectors and actively participate in the joint discussions of the EU One Health Network as defined in paragraph 20;

3. within the One Health Network, discuss the development, progress and implementation of the EU Action Plan;

4. strive for ambitious legislative measures that address the public health risk of AMR, in the areas where there is competence to do it, for example in the area of veterinary medicinal products and medicated feed;

5. develop European Union guidelines on prudent use of antimicrobials in human medicine to support national guidelines and recommendations;

6. set up a voluntary country-to-country peer review system in which representatives from one or several Member States evaluate each other's national action plan, reflect about policy options and provide recommendations to support Member States to improve measures taken. This country-to-country peer review system is complementary to other existing assessment tools or audit activities (e.g. ECDC, Directorate on Health and Food Audits and Analysis[30] or WHO);

7. ensure that the EU has a common approach in the global discussions on AMR, especially on the implementation of the GAP of the WHO, the FAO and the OIE Resolutions on AMR and on the implementation and updating the intergovernmental standards related to AMR published by Codex Alimentarius and the OIE;

8. in the framework of the One Health Network on AMR align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostics, set priorities based on societal needs in the field of public health, animal health and the environment, taking into account the gaps analysis in this domain;

9. actively engage in initiatives and proposals to implement a new business model to bring new antibiotics to the market, including models in which investment costs or revenues are de-linked from sales volumes;

10. encourage all relevant partners, including national regulatory authorities to launch a reflection, within the existing appropriate fora (e.g. the One Health Network), regarding the regulatory framework with regards to antibiotics in order to stimulate research and development and to facilitate marketing authorization procedure for new antimicrobials;

30 The Directorate on Health and Food Audits and Analysis of the European Commission's Directorate-General for Health and Food Safety, formerly the "Food and Veterinary Office".

11. encourage the use of alternative treatment and prevention options including vaccines and the development and use of affordable diagnostics tests in human and veterinary medicine;

12. support in close cooperation between the Member States and the Commission, the proposals ~~s~~ to put AMR on the agenda of the United Nations General Assembly in September 2016, as mandated by the WHO GAP and the FAO Resolutions on AMR, in order to raise awareness of the issue at the highest political level, involving all Heads of State and all relevant UN organisations and aim for ambitious outcomes.

23. CALLS UPON THE COMMISSION TO:

1. facilitate and support Member States in the development, assessment and implementation of national action plans against AMR, including support to strengthen monitoring and surveillance systems and consider financial support within existing frameworks;

2. facilitate and support the regular meetings of the EU One Health Network on AMR as defined in paragraph 20;

3. report to the Council at least once a year on the activities of the One Health Network including the developments in the area of the implementation of the EU Action Plan against AMR;

4. establish a harmonised approach to prevent introduction and spread of emerging antimicrobial resistance in animal husbandry and the food chain with potential impact in public health (e.g. carbapenem resistance);

5. develop as a matter of priority specific acts under the Regulation on transmissible animal diseases ('Animal Health Law')[31] including infection prevention measures, good management practices in animal husbandry and harmonised surveillance systems of relevant animal pathogens;

6. actively promote and defend in multilateral and bilateral dialogues and agreements between the EU and its counterparts the EU standards and EU policies on AMR, especially:

   a) the importance of infection prevention, prudent use of antimicrobials and strengthening the awareness of the risks of AMR in human and veterinary medicine;

   b) the ban on the use of antibiotics as growth promoters in livestock farming;

   c) the avoidance of the routine preventive use of antimicrobials in veterinary practice;

   d) the restrictions on the use in veterinary practice of antimicrobials that are not authorised or which use has been restricted in the EU due to the fact that they are critically important for the prevention and treatment of life-threatening infections in humans;

   e) the EU requirements for the import of live animals and products thereof;

   f) the concept of the precautionary principle[32].

7. promote economic impact studies in the human and animal sector to assess the cost of AMR."

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31 Regulation (EU) No 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

32 See also paragraph 15.

Pharmaceutical systems

The Council adopted the following conclusions on "strengthening the balance in the pharmaceutical systems in the European Union and its Member States":

"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, that the Union shall 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 organization and delivery of health services and medical care and allocation of the resources to them;

2. RECALLS that under Article 168(4)(c) of the Treaty on the Functioning of the European Union, the European Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products and devices for medical use;

3. RECALLS that under Article 4(3) of the Treaty on European Union, the Union and the Member States shall assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation;

4. RECALLS that under Article 5(2) of the Treaty on European Union, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein and that competences not conferred upon the Union in the Treaties remain with the Member States;

5. RECALLS that under Article 3(1)(b) of the Treaty on the Functioning of the European Union, the Union has exclusive competence in relation to the competition rules necessary for the functioning of the internal market for medicinal products;

6. STRESSES that it is fully Member States' competence and responsibility to decide which medicinal products are reimbursed and at what price and that any voluntary cooperation on pricing and reimbursement between Member States should remain Member States driven;

7. RECOGNISES that a balanced and strong, functioning and effective intellectual property environment, that is line with international commitments of the European Union, is important for supporting and promoting access to innovative, safe, effective and quality medicinal products in the European Union;

8. NOTES that the pharmaceutical sector in the European Union has the potential to be a major contributor to innovation and the health and life sciences sector, through the development of new medicinal products;

9. RECOGNISES that new medicinal products however may also pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability;
10. UNDERLINES that Health Technology Assessment is an important tool in achieving sustainable health care systems and to promote innovation that delivers better outcomes for patients and society as a whole and RECOGNISES that EU cooperation in line with the Strategy for EU cooperation on Health Technology Assessment and the adopted work programme of EUnetHTA can support the decision-making of Member States, while acknowledging the potential added value of health technology assessments in the context of national health systems;

11. TAKES NOTE that the EU pharmaceutical legislation provides harmonised regulatory standards for the authorisation and supervision of medicinal products for human use and lays down certain regulatory schemes for the earlier marketing authorisation of medicines with less comprehensive data, such as the conditional marketing authorization or the authorisation under "exceptional circumstances";

12. RECOGNISES that the exact conditions for the inclusion of innovative and specialised medicinal products in the existing schemes of early marketing authorisation could be further clarified in order to improve transparency, to ensure a continuous positive benefit risk balance of medicinal products put on the market under special conditions and to focus on medicinal products of major therapeutic interest for public health or to meet unmet medical needs of patients;

13. BEARING IN MIND that specific legislation has been put in place promoting the development and marketing authorisation of medicinal products targeting – inter alia – products to treat patients suffering from rare diseases commonly known as orphan medicinal products, paediatric medicinal products and advanced therapy medicinal products, incorporating specific incentives, including supplementary protection certificates, data exclusivity or market exclusivity and protocol assistance for orphan medicinal products;
14. BEARING IN MIND that the incentives in this specific legislation need to be proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact, and it should be avoided that circumstances are created that might encourage inappropriate market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems;

15. NOTES that there are indications that the post-market compliance with certain obligations for marketing authorization holders is not always optimal, which may cause that independent research data and information from patient registries are not structurally generated, collected and made available for research and proof of effectiveness and safety;

16. NOTES WITH CONCERN an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances;

17. NOTES the increasing trend of marketing authorisation of new medicinal products for small indications, including, in some cases, the authorisation of a single product for 'segmented' patient groups within a disease area and the authorisation of one substance for several rare diseases and in this respect NOTES WITH CONCERN that companies may seek very high prices while the added value of some of these products is not always clear;
18. RECOGNISES that special attention should be given to the access to medicines for patients in smaller Member States;

19. UNDERLINES the importance of timely availability of generics and biosimilars in order to facilitate patients’ access to pharmaceutical therapies and to improve the sustainability of national health systems;

20. STRESSES that both public and private investments are essential for the research and development of innovative medicinal products. In those cases where public investment has played a major role in the development of certain innovative medicinal products, a fair share of the return on investment in such products should preferably be used for further innovative research in the public health interest for example through agreements made on benefit sharing during the research phase;

21. STRESSES that the functioning of the pharmaceutical system in the EU and its Member States depends on a delicate balance and a complex set of interactions between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products and that several Member States expressed concerns that this system may be imbalanced and that it may not always promote the best possible outcome for patients and society;

22. RECALLS the Council Conclusions on the reflection process on modern, responsive and sustainable health systems adopted on 10 December 2013[1], the Council Conclusions on the economic crisis and healthcare adopted on 20 June 2014[2], the Council Conclusions on innovation for the benefit of patients adopted on 1 December 2014[3] and the Council Conclusions on personalised medicine for patients adopted on 7 December 2015[4];

23. RECALLS the discussion at the Informal Meeting of Ministers of Health in Amsterdam on 18 April 2016 on "Innovative and Affordable Medicines" which highlighted the important role of the life sciences industry in Europe, in particular, in developing effective new treatments for patients with high unmet medical needs. At the same time challenges in the pharmaceutical system in the EU and its Member States were noted and that several Member States may wish to cooperate and take action on a voluntary basis to face common challenges identified by those several Member States to the sustainability of national healthcare systems, which may be linked to a number of potential factors, for example the affordability of medicinal products related to high prices, possible unintended or adverse consequences of incentives and the lack of leverage of individual Member States in negotiations with industry;

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1 OJ C 376, 21.12.2013, p. 3, with Corrigendum in OJ C 36, 7.2.2014, p.6
2 OJ C 217, 10.7.2014, p.2
3 OJ C 438, 6.12.2014, p.12
4 OJ C 421, 17.12.2015, p. 2

24. WELCOMES the discussion during the informal meetings of relevant high level representatives of the Member States responsible for pharmaceutical policy on 11 December 2015 and 26 April 2016, who met for the first time and recognised the added value of an informal reflection and exchange of views on strategic policy level between Member States;

25. RECOGNISES that a number of Member States have expressed interest in pursuing voluntary cooperation between two or more Member States in the field of Health Technology Assessment as well as in exploring voluntary cooperation in different areas, for example on issues related to pricing and reimbursement of medicinal products, activities aimed at 'horizon scanning', the exchange of information and knowledge, the collection and exchange of price data such as the EURIPID collaboration, and in some cases by bringing together of facilities and resources as well as instruments for joint price negotiations and the conducting of early dialogue with companies developing new products; all these activities should remain to be voluntary, focused on clear added value, shared interests and objectives;

26. RECOGNISES that further analysis to examine the current functioning of the pharmaceutical system in the EU and its Member States would be useful, in particular in relation to the impact of certain incentives in EU pharmaceutical legislation, the use thereof by economic operators and the consequences for the innovation, availability, accessibility and affordability of medicinal products for the benefit of patients including as regards innovative treatment solutions to common diseases that cause a heavy burden for individuals and health systems;

27. RECALLS also the relevant findings of the European Commission's 2009 Pharmaceutical Sector Inquiry Report[5], which stressed that a healthy and competitive market for medicinal products benefits from vigilant competition law scrutiny;

[5] 12097/09 + ADD1 + ADD2

28. UNDERLINES the importance of a continuing open and constructive multi-stakeholder dialogue with pharmaceutical industry, patient organizations and other stakeholders, which is necessary in order to ensure future developments of new and innovative medicinal products as well as the sustainability of the pharmaceutical system in the EU and its Member States, while reinforcing, at the same time, public health interests and guaranteeing the sustainability of the EU Member States health systems;

29. RECOGNISES that the pharmaceutical system in the EU and its Member States, which is characterised by a division of competences between Member States and the EU level, can benefit from dialogue and a more holistic approach regarding pharmaceutical policy, by enhancing voluntary cooperation between Member States aimed at greater transparency, to safeguard common interests, ensuring access of patients to safe, effective and affordable medicinal products as well as the sustainability of national health systems;

30. RECALLS the Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015 [6] published by the European Medicines Agency and EUnetHTA;

31. RECOGNISES potential benefits of the exchange of information across Member States on implementation and application of Managed Entry Agreements;

32. RECOGNISES that while these Council conclusions mainly refer to medicinal products, given the specific nature of the sector, the same concerns regarding sustainability and affordability, as well as considerations regarding research and development and HTA, are also applicable to medical devices and in-vitro diagnostic medical devices.

6 http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/04/WC500204828.pdf

INVITES THE MEMBER STATES TO:

33. Consider further development of exclusively Member States driven voluntary cooperation between relevant authorities and payers from Member States, including cooperation within groups of Member States, that share common interests in relation to pricing and reimbursement of medicinal products and to explore possible areas in which such voluntary cooperation can contribute to higher affordability and better access to medicinal products. Where relevant and appropriate, groups of Member States that would like to explore cooperation on a voluntary basis, may also make use of international expertise, with full respect of Member States' competences. This voluntary cooperation could include activities such as:

- Assessment of future introduction of new medicinal products with a possibly significant financial impact on health systems at an early stage through so called 'joint horizon scanning', which entails a forward looking scan of emerging trends and future developments in pharmaceutical research and development aimed at better anticipating the arrival of new, expensive, innovative medicinal products that might potentially affect current policy and practice;

- Pro-active exchange of information between Member States (e.g. national pricing and reimbursement authorities), particularly in the pre-launch phase, with due respect for existing national rules and frameworks, e.g. in relation to business confidentiality;

- Exploring possible strategies on voluntary joint price negotiations in coalitions of Member States, that have expressed interest to do so;

- Consider reinforcing existing cooperation schemes and initiatives to foster agreement on approaches to address unavailability of medicinal products and market failure situations.

34. Exchange HTA-methodologies and assessment outcomes through EUnetHTA and the HTA Network as already foreseen under the Joint Action EUnetHTA, while recognizing that financial impact and pricing must be addressed separately from the HTA, and that the applicability of HTA results need to be assessed by national health systems.

35. Without prejudice to existing cooperation in the context of EUnetHTA, and where appropriate, further explore closer voluntary cooperation on HTA between two or more Member States as a Member States' initiative, such as mutual recognition of HTA reports and/or joint HTA reports.

36. Consider organising during each EU Presidency an informal meeting of relevant high level representatives from the Member States responsible for pharmaceutical policy (e.g. national directors of pharmaceutical policy), encouraging strategic reflection and discussion on current and future developments in the pharmaceutical system in the EU and its Member States, thereby avoiding duplication and respecting the division of competences. These discussions are purely informal and, where relevant and appropriate, can be used as an input for further reflection in the appropriate EU fora, in particular the Working Party on Pharmaceuticals and Medical Devices when areas of EU competence are concerned.

37. The Presidency-trio (the Netherlands, Slovakia and Malta) is invited to identify with the Member States a set of mutual experienced concerns and challenges which could be considered and/or modified by the future Presidencies in the period from 2017-2020, with full respect for Member States' and EU level competences.

38. Where appropriate, these common concerns and challenges will be followed up concretely through dialogue, exchange and (international) cooperation as well as through information exchange, monitoring and research at Member States and EU level in the appropriate fora and, in particular, when EU competences are concerned, through the Working Party on Pharmaceuticals and Medical Devices, with the input from Member States, existing technical and policy fora and, where relevant, the European Commission.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

39. Explore possible synergies between the work of regulatory bodies, HTA bodies and payers, whilst respecting their specific responsibilities in the pharmaceutical chain and fully respecting Member States competences, in order to ensure timely and affordable access of patients to innovative medicinal products that reach the market especially through EU regulatory tools of accelerated assessment, marketing authorisation in exceptional circumstances and conditional marketing authorisation while also analysing the effectiveness of these tools and examining possible clear and enforceable (pre-) conditions and exit options for the products that enter the market through these mechanisms in order to ensure high level of quality, efficacy and safety of the respective medicinal product. These products will therefore continue to be appropriately evaluated and examined with regard to their benefits and risks and appropriateness to be included in these tools.

40. Foster enhanced cooperation between Member States under the 3rd Joint Action of the European Network for Health Technology Assessment (EUnetHTA) as adopted and to reflect about the future of HTA cooperation at European level for the period beyond 2020 when the current Joint Action comes to an end.

41. Improve and strengthen existing dialogue and cooperation between Member States and at EU level, in particular through and within existing fora and technical working bodies and by continuing investment in and facilitating the work of the Network of Competent Authorities on Pricing and Reimbursement (NCAPR), the Pharmaceutical Committee and the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP).

42. Assess the relevance and functioning of the various technical bodies operating at EU level within the EU pharmaceutical framework, including those operating under the auspices of the European Commission, to clarify and confirm existing tasks, roles and mandates with the aim to avoid duplication and fragmentation of work, and to give Member States a better insight and overview of ongoing developments and discussions in these fora.

43. Consider further investments at national and EU level in the availability of registries and in the developments of methods to assess the effectiveness of pharmaceuticals including through the use of relevant digital means. The implementation of means to inform on post-marketing effectiveness of medicines should allow exchange of information between Member States although in full respect of individual competences, applicable legislation on data protection and other legislation.

44. Consider further investments at national and EU level in the development of innovative medicines for clearly defined unmet medical needs, in particular also through Horizon2020 and the Innovative Medicines Initiative (IMI) and with the involvement of the European Medicines Agency, whilst promoting open access to research data while fully respecting applicable legislation on data protection and, where applicable, the information that is considered commercially confidential, and considering conditions such as equitable licensing to ensure a fair return on investment for publicly funded research that delivered a major contribution to the development of successful medicinal products.

45. Explore obstacles for deploying existing methods and consider new solutions to address market failure, in particular also in small markets, when established products become unavailable or new products are not introduced to national markets, for example for business economic reasons.

INVITES THE EUROPEAN COMMISSION TO:

46. Pursue the ongoing activities to streamline the implementation of the current legislation on orphan medicinal products and to ascertain correct application of the current rules and fair distribution of incentives and rewards and if necessary consider revision of the regulatory framework on orphan medicinal products without discouraging the development of medicinal products needed for the treatment of rare diseases.

47. Prepare as soon as possible and with the close involvement of the Member States, while fully respecting Member States competences, the following:

a. an overview of the current EU legislative instruments and related incentives that aim to facilitate the investment in the development of medicinal products and the marketing authorization of medicinal products given to the holders of a marketing authorisation as implemented within the EU: Supplementary Protection Certificates (Regulation EC 469/2009), medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), orphan medicinal products (Regulation EC 141/2000) and paediatrics (Regulation EC 1901/2006);

b. an evidence based analysis of the impact of the incentives in these EU legislative instruments, as implemented, on innovation, as well as on the availability, inter alia supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Among those incentives, particular attention should be given to the purpose of supplementary protection certificates as defined in the relevant EU legislative instrument and the use of the "Bolar" patent exemption[7], the data exclusivity for medicinal products and the market exclusivity for orphan medicinal products.

Where relevant, the analysis of impacts should also address – inter alia - the development of medicinal products and the effects of the pricing strategies of industry in relation to these incentives.

[7] Article 10.6 of the Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

The Commission will conduct the analysis on the basis of the information that is made available or gathered, including from the Member States and other relevant sources.

To this end, the Commission should prepare by the end of 2016 a timetable and methodology for conducting the analysis as mentioned in this paragraph.

48. Continue and where possible intensify, including through a report on recent competition cases following the pharma sector inquiry of 2008/ 2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation 139/2004) and the monitoring, methods development and investigation - in cooperation with national competition authorities in the European Competition Network (ECN) – of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union.

49. Based on the above mentioned overview, analysis and report in paragraphs 39 and 40, and taking into account the international commitments of the EU and – inter alia– also the needs of the patient, health systems and the competitiveness of the EU based pharmaceutical sector, discuss the outcome and possible solutions proposed by the Commission in the Working Party on Pharmaceuticals and Medical Devices and, when public health issues are concerned, the Working Party on Public Health at Senior Level."

Any other business

- **Medical devices**

  The presidency informed the Council about the agreement reached with the European Parliament on new EU rules for medical devices and on in vitro diagnostic medical devices (9490/16 + 9365/3/16 REV 3 + 9364/3/16 REV 3). Ministers welcomed the deal, thanked the presidency for its efforts and looked forward to the future adoption of the two new regulations.

- **Milk for young children and food for sports people**

  The Commission presented its report on young child formulae; the Commission also presented its report on food intended for sports people.

- **Standardisation of healthcare services**

  The Polish delegation shared its views on the European Committee for Standardisation 2016 work programme.

- **Election of the WHO Director-General**

  The French delegation provided ministers with information on the election of the next WHO Director-General.

- **State of health in the EU**

  The Commission briefed ministers on the "State of Health in the EU"-package that it intends to deliver in 2016-2017.

- **Endocrine disruptors**

  The Commission presented the criteria that it intends to use for identifying endocrine disruptors.

- **European fund for strategic investment**

  The Commission informed ministers about how best to use the European fund for strategic investment for innovative financing in healthcare.

- **Response to Zika**

  The Commission informed the Council about the support that it has already provided to member states in response to the Zika virus outbreak and the support that it intends to provide.

- **Health systems performance assessment**

  The Commission informed ministers about the work of the expert group on health systems performance assessment.

- **Conferences**

  The Netherlands presidency informed the Council about the outcomes of the conferences in the field of health that it organised during its mandate.

- **Work programme of the incoming presidency**

  The Slovak 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

ECONOMIC AND FINANCIAL AFFAIRS

Bank capital requirements

The Council decided not to object to a Commission regulation amending regulatory technical standards set under directive 2013/36/EU on bank capital requirements (9732/16 + 9042/16).

The regulation amends regulation 1222/2014 as concerns the methodology used to identify global systematically important institutions and subcategories of such institutions.

It is a delegated act pursuant to article 290 of the Treaty on the Functioning of the European Union. It can now enter into force, unless the European Parliament objects.

TRADE POLICY

WTO waiver - Western Balkans

The Council adopted a decision providing for a request to be made to extend a WTO waiver on autonomous trade preferences granted by the EU to the Western Balkans (9549/16 + 8683/16).

The request will be made within the WTO's General Council to extend the trade preferences until 31 December 2021.

FISHERIES

Sri Lanka removed from the list of third countries not cooperating in the fight against illegal, unreported and unregulated fishing

The Council adopted amendments to implementing decision 2014/170/EU establishing a list of non-EU countries not cooperating in the fight against illegal, unreported and unregulated fishing (8560/16).

The amended decision concerns the removal of Sri Lanka from that list in view of Sri Lanka’s improved compliance with international obligations in this field, its introduction of a more efficient control and monitoring system and its assurances with regard to implementing the catch certification scheme.

TELECOMMUNICATIONS

Inland waterway vessels – uniform technical requirements

The Council adopted its position at first reading on a directive laying down technical requirements for inland waterway vessels. The revised draft directive sets out how the EU will apply the technical standards developed by the European Committee for drawing up standards in the field of inland navigation (CESNI), which was set up under the auspices of the Central Commission for Navigation of the Rhine (CCNR) in June 2015.

This adoption by the Council of its position at first reading paves the way for final approval by the European Parliament at second reading.

Inland waterway vessels: Council adopts directive on uniform technical requirements

Technical requirements for inland waterway vessels - Council position at first reading

Technical requirements for inland waterway vessels - Council's reasons

Technical requirements for inland waterway vessels - statement

Web and app accessibility

The Council adopted a political agreement on the first rules to make public sector websites and mobile applications (apps) more accessible across the EU.

An informal agreement on the proposal was reached with the Parliament on 3 May 2016. The deal was confirmed by the Permanent Representatives Committee on 25 May.

The text will now undergo legal-linguistic revision. After that, the Council is due to adopt its position at first reading, paving the way for final approval by the European Parliament at second reading.

Draft directive on the accessibility of public sector bodies' websites

More accessible websites across Europe: agreement with European Parliament

STATISTICS

Statistics on external trade

The Council adopted its first-reading position with a view to amending regulation 471/2009 on statistics relating to external trade with non-EU countries (8536/16 and 8536/16 ADD1).

The Council's position, which follows a political agreement with the European Parliament, is expected to be confirmed by the Parliament with a second-reading vote at an upcoming plenary session.

The amendments to regulation 471/2009 will mainly adapt the delegated and implementing powers to be conferred to the Commission for the adoption of measures related to changes in the Customs Code, provisions deriving from international conventions and changes needed for methodological reasons to improve the system for the collection of data.

The statistical information on EU member states′ trade flows with non-member countries is of essential importance for the EU's economic and trade policies and for analysing market developments for goods.

External trade statistics are based on data obtained from customs declarations.

APPOINTMENTS

Court of Auditors

The Council appointed Mr Rimantas ŠADŽIUS (Lithuania) as a member of the Court of Auditors for the period from 16 June 2016 to 15 June 2022 (9381/16).

TRANSPARENCY - PUBLIC ACCESS TO DOCUMENTS

On 16 June 2016, the Council approved:

- the reply to confirmatory application No 11/c/01/16 (9981/16)