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3323rd Council meeting

Employment, Social Policy, Health and Consumer Affairs

Luxembourg, 19 and 20 June 2014

Presidents **Ioannis VROUTSIS**

Minister for Employment, Social Protection and Welfare of

Greece

Makis VORIDIS

Minister for Health of Greece

PRESS

Main results of the Council

Employment and Social Policy

The Council held a policy debate on the **European Semester 2014** in the field of employment and social policy and approved the employment and social policy aspects of the country-specific recommendations.

The President of the Council, Mr Ioannis Vroutsis, declared: "Through close cooperation with the other member states, the Hellenic Presidency has left its mark by achieving agreements on numerous dossiers that are important for the European integration. Moreover, I believe that we succeeded in developing tools and policies which will help us to respond to the needs and demands of our citizens and to meet their expectations for a decent life, quality jobs and opportunities for a lifelong career development."

The Council discussed the social dimension of the **EU/EMU** on the basis of reports drafted by the Social Protection Committee.

The Council adopted <u>conclusions</u> on "Women and the economy: Economic independence from the perspective of part-time work and self-employment".

Ministers took note of progress reports on:

- a decision establishing a new Platform to improve prevention and deterrence of undeclared work,
- a regulation regarding the EURES (EURopean Employment Services) network,
- a directive on women on company boards, and
- the **equal treatment** directive.

Health

The Council provided guidance for future work on two draft regulations concerning **medical** devices and in vitro medical devices with a view to agreeing on a Council position in autumn.

"The aim is to define a framework for production and placing on the market of medical devices restoring trust among consumers, users and stakeholders while ensuring a high level of health protection. Improvements in medical technology can contribute to creating new jobs and reduce overall costs while improving the effectiveness of our health care systems", *said Makis Voridis*, *Minister for Health of Greece and President of the Council*.

Ministers also adopted conclusions on

- the economic crisis and healthcare outlining the impact that the economic crisis had on the healthcare systems in the EU and suggesting ways to make them more resilient;
- Nutrition and physical activity, encouraging member states to promote a healthy diet and physical activity in order to reduce the burden of chronic and non-communicable diseases such as hypertension.

In the margins of the Council meeting, 15 member states signed a **joint procurement agreement for pandemic vaccines** and other medical countermeasures, and eight member states signed a letter expressing their intention to sign the agreement. The objective of the agreement is to help member states to ensure that pandemic vaccines and medicines are available in sufficient quantities and at an advantageous price if a cross border health threat emerges.

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OTHER ITEMS APPROVED

none

[•] 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.

PARTICIPANTS

Belgium:

Mr Philippe COURARD State Secretary for Social Affairs, Families and the

Disabled, with responsibility for Occupational Hazards, attached to the Minister for Social Affairs and Public Health, and State Secretary for Science Policy, attached to

the Minister for Social Affairs and Public Health

Bulgaria:

Ms Svetlana DIANKOVA Deputy Minister for Labour and Social Policy

Minister for Health

Czech Republic:

Ms Tanya ANDREEVA-RAYNOVA

Ms Michaela MARKSOVÁ Minister for Labour and Social Affairs

Mr Vladimír VALENTA Deputy Minister for Public Health Protection and Health

Promotion

Denmark:

Ms Mette FREDERIKSEN Minister for Employment

Mr Ole TOFT Deputy Permanent Representative

Germany:

Ms Andrea NAHLES Federal Minister for Labour and Social Affairs

Estonia:

Ms Helmen KÜTT* Minister for Social Affairs
Mr Clyde KULL Deputy Permanent Representative

Ireland:

Mr Richard BRUTON Minister for Jobs, Enterprise and Innovation

Mr James REILLY Minister for Health

Greece:

Mr Ioannis VROUTSIS Minister for Employment, Social Protection and Welfare

Mr Mavroudis VORIDIS Minister for Health

Spain:

Mr José Pascual MARCO MARTÍNEZ Deputy Permanent Representative

Ms Pilar FARJAS Secretary General for Health and Consumer Affairs

France:

Mr François REBSAMEN Minister for Labour, Employment and Social Dialogue

Mr Alexis DUTERTRE Deputy Permanent Representative

Croatia:

Mr Mirando MRSIĆ Minister for Labour and the Pension System

Mr Siniša VARGA Minister for Health

Ms Milanka OPAČÍĆ Deputy Prime Minister and Minister for Social Policy and

Youth

Italy:

Mr Giuliano POLETTI Minister for Labour and Social Policy

Mme Beatrice LORENZIN Minister for Health

Cyprus:

Ms Maria HADJITHEODOSIOU Deputy Permanent Representative

Mr Philippos C. PATSALIS Minister for Health

Latvia:

Ms Ieva JAUNZEME
Mr Rinalds MUCIŅŠ
State Secretary, Ministry of Welfare
State Secretary, Ministry of Health

Lithuania:

Ms Algimanta PABEDINSKIENE Minister for Social Security and Labour

Mr Vytenis Povilas ANDRIUKAITIS Minister for Health

Luxembourg:

Mr Nicolas SCHMIT Minister for Labour, Employment and the Social and

Solidarity Economy

Mr Romain SCHNEIDER
Minister for Social Security, Minister for Development
Cooperation and Humanitarian Affairs, Minister for Sport

Mr Georges FRIDEN**

Deputy Permanent Representative

Hungary:

Mr Olivér VÁRHELYI Deputy Permanent Representative

Malta:

Mr Michael FARRUGIA Minister for the Family and Social Solidarity

Mr Chris FEARNE Parliamentary Secretary for Health within the Ministry for

Energy and Health

Netherlands:

Mr Lodewijk ASSCHER Deputy Prime Minister, Minister for Social Affairs and

Employment

Mr Wepke KINGMA Deputy Permanent Representative

Austria:

Mr Rudolf HUNDSTORFER Federal Minister for Labour, Social Affairs and Consumer

Protection

Mr Harald GÜNTHER Deputy Permanent Representative

Poland:

Mr Radosław MLECZKO Deputy State Secretary, Ministry of Labour and Social

Policy

Mr. Igor RADZIEWICZ-WINNICKI Deputy State Secretary, Ministry of Health

Portugal:

Mr Paulo MACEDO Minister for Health

Mr Pedro COSTA PEREIRA Deputy Permanent Representative

Romania:

Ms Rovana PLUMB Minister of Labour, Family, Social Protection and the

Elderly

Mr Răzvan VULCĂNESCU Deputy State Secretary, Ministry of Health

Slovenia:

Ms Martina VUK State Secretary in the Ministry of Labour, Family, Social

Affairs and Equal opportunities

Ms Nina PIRNAT State Secretary at the Ministry of Health

Slovakia:

Mr Branislav ONDRUŠ State Secretary of Labour, Social Affairs and Family

Mr Alexander MICOVČIN Deputy Permanent Representative

<u> Finland:</u>

Ms Tuire SANTAMÄKI-VUORI State Secretary, Ministry of Employment and the

Economy

Ms Marianne HUUSKO-LAMPONEN Deputy Permanent Representative

Sweden:

Ms Elisabeth SVANTESSON Minister for Employment

Ms Lena FURMARK State Secretary, Ministry of Social Affairs

United Kingdom:

Ms Shan MORGAN Deputy Permanent Representative

Commission:

Mr Neven MIMICAMemberMr Lázló ANDORMemberMr Tonio BORGMember

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ITEMS DEBATED

EMPLOYMENT AND SOCIAL POLICY

European Semester 2014

Under this year's European Semester, the EPSCO Council held a policy debate approving its contributions to the European Council on the employment/social policy aspects of the country-specific recommendations (CSRs) and the results of the multilateral surveillance.

This year's process is all the more important as it takes place in the midst of a gradual, but still fragile recovery. The objectives remain clear: the momentum of the ongoing structural reforms has to be maintained if lasting results are to be achieved.

Overall, the discussions reflected broad agreement on the common challenges such as the sustainability of pensions and strengthening the resilience of the labour markets. Significant measures have been taken by member states in terms of combatting labour market segmentation, preventing early labour market withdrawal and in putting in place a Youth Guarantee.

Further progress has still to be made to ensure that active labour market policies become more efficient, including the increase in female participation.

Against the background of increasing poverty, there is also an urgency to ensure an adequate level of social protection. Efforts need to continue to improve the efficiency and effectiveness of social protection systems.

On pensions, most member states consider that first closing the gap with the effective retirement age is the most urgent issue. Raising the statutory retirement age should not be the one-size-fits-all option. In addition, pension adequacy will constitute a major political and social challenge for the years to come.

One of the biggest challenges is the growing divergences in the employment and social situations of member states within the euro area. As a result of the economic crisis, some member states are confronted with declining household disposable income, rising inequalities, poverty and social exclusion.

In the context of the policy debate, the Council endorsed an opinion of the Employment Committee (EMCO) on the national reform programmes (2014) and the implementation of the 2013 country-specific recommendations (10338/14).

It endorsed the key messages of an assessment of the 2014 package of Council recommendations on cross-cutting issues prepared by the Social Protection Committee (SPC) (10814/14). These key messages identify key social protection and inclusion issues in the 2014 package and include considerations on the European Semester governance.

The Council also endorsed the employment performance monitor and benchmarks ($\underline{10763/14}$) as well as a joint EMCO-SPC opinion on the scoreboard of employment and social indicators ($\underline{10337/14 + ADD\ 1}$). The scoreboard is one of the main instruments for the strengthening of the social dimension of the EMU and the European Semester. Its objective is to enhance the capacity to identify at an early stage the major employment and social trends which can severely undermine employment and social cohesion in the euro area and the EU at large. This should be achieved through a full integration between the scoreboard and the existing social monitoring instruments.

It also endorsed a report on the implementation of the Youth Guarantee (10339/14).

The social dimension of the EU/EMU

The Council took stock of the latest developments regarding the social dimension of the EU/EMU on the basis of four reports of the Social Protection Committee (SPC).

Ministers had an exchange of views which the Presidency summarised as follows: The economic policy, the employment policy and the social policy are interlinked and constitute the main pillars of a sustainable development policy. For that reason and taking into account the principle of subsidiarity, we have to promote, in the context of an holistic approach, the coordination of all these policy areas. The review of the Europe 2020 strategy constitutes a unique opportunity to promote coordination and closer cooperation between the different Council configurations. A critical aspect for success will be the further development and strengthening of the social governance of the EU. Social investment and efficient systems of social protection will contribute to address the social impact of the crisis. Crucial is also the role of minimum income schemes which have to provide for a decent life.

The employment and social scoreboard is being applied this year for the first time. It clearly indicates the impact of the crisis on employment and social cohesion, resulting into a growing divergence between member states. An increasing polarisation within societies is noted. This runs counter the objectives of the EMU. At the same time, the most recent data also demonstrate that the EU is drifting away from the 2020 poverty reduction targets.

This worrying situation will only be improved if the EU is able to give substance to a social dimension for the EMU. In defining and implementing its policies, the EU has to take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion and a high level of education, training and protection of human health. To develop a deeper EMU, a coherent vision of what needs to be done is required.

The SPC reports concern:

- **Social dimension of the Europe 2020 strategy** (10403/14): The report recommends that in the remaining years to 2020, the fight against poverty, inequalities and social and labour market exclusion should remain a high priority for member states and the EU. The strategy needs to support member states in their efforts to strengthen social investment across policies. The focus should be on investing in human capital development, activating labour market participation, and improving the capacity of social protection systems to provide an effective protection against the risks that people face across the life cycle.
- Ex-ante coordination of major social policy reforms (10386/14): The report focuses on the outcome of a feasibility test during which plans for major policy reforms by some volunteering member states (CY, EE, IT, SI and RO) in areas falling under the EPSCO remit were examined. This approach is consistent with the work carried out by the Economic Policy Committee (EPC) and responds to the European Council conclusions of 25 October 2013, which called for further enhancement of the coordination of the economic, employment and social policies and for strengthened cooperation between the Council configurations in order to ensure the consistency of those policies.
- Minimum income schemes in the euro area (<u>10407/14</u>): The report indicates that almost all of euro area member states have in place provisions for granting means-tested minimum income benefits to eligible individuals and households. The remaining member states are taking preparatory measures for developing such schemes. The level of these benefits varies across the euro area and reflects country-specific economic and social conditions and political choices.
- Adequate social protection for long-term care needs in an ageing society (<u>10406/14+ADD I</u>): This report, which was endorsed by the Council, examines what can be done to help member states reduce the risk of a gap emerging and ensure that adequate provisions for long-term care needs can be organised in a sustainable way even with an ageing population.

Long-term care encompasses a range of services and support for people who are dependent on help with their daily living over a long period of time. This need is usually the result of disability caused by health problems and therefore may affect people of all ages. But the great majority of the recipients of long-term care are older people.

Increasingly, long-term care in the EU will be facing three major, related and simultaneous challenges. The first is a huge increase in need. Over the next five decades the number of Europeans aged over 80 and at risk of needing long-term care is expected to increase threefold. The second is the threat to the supply of long-term carers from the decline in the number of people of working age, and from social changes which make it less likely in the future that families will provide the informal, home-based care on which the great majority of older people now rely. The third is the pressure that rapid growth in demand and the expectations of the "baby boom" generation will place on care quality, enforcement of care standards and on public expenditure.

EU platform against undeclared work

The Council took note of a progress report on a decision establishing a Platform to improve cooperation at EU level in order to prevent and deter undeclared work more effectively (10871/14).

Many ministers expressed appreciation for the rapid progress made on this dossier during the Hellenic presidency and regretted that the Council was not in a position to agree a general approach. They called for the completion of the discussions as soon as possible under the Italian presidency.

The Platform will aim to facilitate the exchange of best practices and information, provide a framework at EU level to develop expertise and analysis, and promote joint actions between the different national enforcement authorities of member states.

The proposal envisages the participation of all member states in the Platform, as this is crucial to address cross-border situations. Each member state would be invited to nominate a single contact point.

The Platform should involve the social partners at EU level, both cross-industry and in those sectors more severely affected by undeclared work, and cooperate with the relevant international organisations such as the International Labour Organisation and the EU's decentralised agencies, in particular Eurofound and the European agency for safety and health at work.

The Platform would work on the basis of two-year work programmes, setting out its detailed tasks covering all aspects related to undeclared work such as labour law, labour inspections, health and safety, social security, tax and migration. It would also regularly inform the European Parliament and the Council about its activities.

EURES (EURopean Employment Services) network

The Council took stock of progress on a regulation which establishes new rules improving EURES efficiency as well as the cooperation among member states (10130/14).

The aim of the proposal is to support fair mobility by enhancing access to labour mobility support services, thus assisting workers in overcoming barriers to mobility and increasing access to employment opportunities throughout the EU.

An important element of the proposal is the re-establishment of the EURES network, addressing the shortcomings identified to date in the current framework for cooperation based on regulation 492/2011, and aiming to adapt the EURES network to the current market needs by also supplying a solid and adequate legal basis.

On 17 January 2014, the Commission adopted the above proposal and the Council working party examined it on several meetings.

During the discussion in the Council working party, the delegations took the view that the proposal was useful in its aim of facilitating mobility, thus helping to tackle the issue of unemployment in Europe by better matching supply and demand in the labour market.

Women on company boards

The Council took note of a progress report on a directive improving the gender balance on company boards (9864/1/14 REV I).

During the Hellenic Presidency, the Council working party discussions have revealed a broad consensus in favour of the proposal's objective; nevertheless opinions continue to differ sharply regarding the best way of achieving it.

While all delegations are in principle in favour of improving gender balance on company boards, a number of delegations continue to prefer national measures (or non-binding measures at the EU level) whereas others support EU-wide legislation. During the Hellenic Presidency, the working party has mainly concentrated its work on technical aspects. Further work and political reflection will be required before a compromise can be reached.

The Commission's proposal would seek to increase the proportion of the under-represented sex to 40% of non-executive board members by 2020. This is not a hard quota but a binding objective that would be achieved by applying certain rules in the selection procedure.

Equal treatment

The Council took note of a progress report (<u>10038/1/14 REV 1</u>) on the equal treatment directive in terms of religion or belief, disability, age or sexual orientation. The directive prohibits discrimination in the following areas: social protection, including social security and healthcare; social advantages; education; and access to goods and services, including housing.

The proposed directive, which requires unanimity, has been on the Council's agenda since 2008. The Hellenic Presidency has advanced the work on certain issues, including the concept of discrimination and the scope.

Nevertheless, certain delegations still have general reservations, questioning the need for the proposal, which they believe infringes upon national competences and conflicts with the principles of subsidiarity and proportionality. Other delegations have concerns relating, in particular, to the lack of legal certainty, the division of competences, and the practical, financial and legal impact of the proposal.

"Women and the economy: Economic independence from the perspective of part-time work and self-employment"

The Council adopted conclusions on "Women and the economy: Economic Independence from the perspective of part-time work and self-employment" (9711/14).

The conclusions are based on a report prepared by the European institute for gender equality and focus on the vital issue of equal economic independence.

They include a set of three new indicators. These indicators will improve our understanding of the labour market experience of women and men by showing the rates of full-time equivalent work, part-time work and self-employment for women and men. The indicators also give an insight into the extent to which part-time work is a voluntary preference.

Employment is the bedrock of economic independence. Yet not all workers have full-time jobs. Part-time work has the potential to enhance women's economic independence. Working part-time can also facilitate work-life balance. On the other hand, it can also create unfair differences in pay, working conditions and career advancement.

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Any other business

Dossiers completed under the Hellenic Presidency

The Presidency informed the Council about the legislative dossiers it had finalised, namely the posting of workers directive, the decision on the creation of a network of public employment services and the regulation on the Fund for the most deprived.

International Labour Organisation conference 2014

The Presidency and the Commission informed ministers about the outcome of the 103rd International Labour Organisation conference which took place in Geneva from 28 May to 12 June 2014.

Roma summit

The Commission informed the Council on the third European Roma summit which took place in Brussels on 4 April.

Ratification and implementation of the UN Convention on the rights of people with disabilities

The Commission informed the Council about he ratification and implementation of the UN Convention on the rights of people with disabilities.

Work programme of the incoming Presidency

The Italian delegation informed ministers about its work programme in the field of employment and social policy.

HEALTH

Medical devices

The Council took note of a presidency progress report on two draft regulations on medical devices and on *in vitro* diagnostic medical devices (<u>10855/14</u>). Ministers provided guidance for future work on these files as regards the three following elements:

- the designation of conformity assessment bodies as notified bodies and the monitoring of these bodies;
- the reporting of incidents, market surveillance and corrective measures;
- the role and tasks of the medical device coordination group (MDCG).

As far as the notified bodies are concerned, most member states supported the idea of further clarifying the procedures for designating notified bodies and strengthening cooperation between member states to ensure that notified bodies meet similar standards throughout the EU. But they also warned against increasing the administrative burden unnecessarily.

All member states supported strengthened requirements on post-market surveillance and responsibility for follow-up by manufacturers. However, as regards the balance between controls before and after placing devices on the market there were diverging views.

All delegations welcomed the establishment of the MDCG but some warned against overburdening it with too many tasks. Many member states stressed the need to develop a consistent legislative package that guarantees patient safety and facilitates innovation in order to improve treatments, decrease costs for patients and taxpayers, and preserve the competitiveness of the EU industry.

The Council instructed its preparatory bodies to continue examining the two files with a view to agreeing a Council position in the autumn.

The revision of the EU laws on medical devices is aimed at ensuring the highest level of protection for European patients, consumers and healthcare professionals, and to ensure that safe, effective and innovative medical devices can be placed on the market and made available to users in a timely manner. The new regulations should thus benefit both patients and European competitiveness.

Medical devices cover a huge spectrum of products, ranging from sticking plasters, corrective glasses or dental filling material to bone screws, heart valves and breast implants, and also including all X-ray or scanner machines. Likewise, there is a wide range of *in vitro* diagnostic medical devices which include, for instance, blood tests and other products which provide information on physiological or pathological states.

Unlike medicinal products medical devices and *in vitro* diagnostic medical devices are not subject to any pre-market authorisation but to a conformity assessment which, depending on the risk potential of the product, involves an independent third party, the notified body. Notified bodies are designated and monitored by the member states and act under the control of the national authorities.

The Commission proposals $(\underline{14493/12} + \underline{14499/12})$ contain the following key elements:

- The **scope** of the current EU rules on medical devices is **extended**, for instance, to implants for aesthetic purposes, and, as far as *in vitro* **diagnostic medical devices** are concerned, for example to tests providing information about any predisposition to a disease (e.g. **genetic tests**).
- Economic operators must be able to identify who supplied them and to whom they have supplied medical devices; manufacturers must fit their products with a unique device identification to ensure traceability.
- Manufacturers and importers of both categories of products must register themselves and the devices they place on the EU market in a central European database.
- Patients who are implanted with a device must be given essential information on the
 implanted product, including any necessary warnings or precautions to be taken, for
 example on whether or not it is compatible with certain diagnostic devices or with
 scanners.
- An EU portal is created where manufacturers must report serious incidents and any corrective actions they have taken to reduce the risk of recurrence.
- Notified bodies acquire the right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on medical devices and *in vitro* devices.

The economic crisis and healthcare

The Council adopted conclusions on the economic crisis and healthcare, set out in (10463/14).

The conclusions outline the impact that the economic crisis had on the healthcare systems in the EU and suggest ways to make it more resilient. They note with concern that public health expenditures has decreased in many member states since 2009, and that although most member states have universal coverage, in practice many people have problems in accessing healthcare services when they need them. Recalling the discussions at the informal meeting of health ministers in Athens on 28-29 April, which stressed the importance of health reforms to overcome the crisis, the conclusions identify a number of areas where action is needed. These include considering innovative ways of integration between primary and hospital care, and promoting the implementation of information and communications technology and eHealth solutions.

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Nutrition and physical activity

The Council adopt conclusions on nutrition and physical activity, set out in (10122/14).

The conclusions take stock of the current situation where more than half of the adult population in the EU is overweight or obese according to the body mass index of the WHO. They note that up to 7% of EU health budgets is spent each year directly on diseases linked to obesity and deplore the low consumption of fruit and vegetables and the high intake of saturated fats, trans fatty acids, salt and sugar as well as the shift towards sedentary lifestyles. The conclusions also set out a number of measures to be undertaken in order to promote healthy diet and physical activity, in order to reduce the burden of chronic and non-communicable diseases such as hypertension, heart disease, diabetes, stroke and osteoporosis. They call, for instance, on the member states and the Commission to support the implementation of national food and nutrition action plans, and to promote action to reduce the exposure of children to advertising, marketing and promotion of foods high in saturated fats, trans fatty acids, added sugars or salt. The conclusions build on the outcomes of the Athens high-level conference on "Nutrition and Physical Activity from Childhood to Old Age: challenges and opportunities" held on 25-26 February 2014.

Any other business

Joint plan for immediate actions for medical devices

The Commission informed the Council on the implementation of the joint plan for immediate actions under the existing medical devices legislation and further steps (10343/14). The Commission launched its joint plan in February 2012 to address the need for immediate action at national level to ensure full and stringent implementation of the current legislation on medical devices. Many delegations stressed the importance of building on the experience from the joint action plan for the work on the revision of the legislation on medical devices and *in vitro* medical devices.

Joint procurement agreement for medical countermeasures

The Commission informed the Council on the joint procurement agreement for medical countermeasures (<u>10924/14</u>). The joint procurement agreement allows member states to join forces and purchase together vaccines and other medical countermeasures needed to fight serious cross-border threats to health. The aim is to ensure that member states are able to secure vaccines and other medicines for their populations under better conditions than in the past.

Plain packaging of tobacco products

The Irish delegation informed the Council that with its public health bill approved by the Irish government on 10 June, Ireland was the first EU country to introduce standardised packaging of tobacco products (<u>10876/14</u>).

Standardised packaging of tobacco products removes all forms of branding - trademarks, logos, colours and graphics. The brand name is presented in a uniform typeface for all brands and the packs are in one plain neutral colour.

Australia was the first country in the world to introduce plain packaging on 1 December 2012.

Prices of innovative medicines

Drawing the Council's attention to the high price of medicines for hepatitis C the French delegation suggested creating a network for information exchange among member states (10854/14). The prices charged for the new hepatitis C medicines were unsustainable for member states' health budgets. The French initiative received the support of many member states.

Work programme of the incoming presidency

The Italian delegation will inform ministers about its work programme in the field of health and consumer affairs as the incoming Presidency of the Council of the EU.

Signing ceremony of the joint procurement agreement

In the margins of the Council, 15 member states signed a joint procurement agreement for pandemic vaccines and other medical countermeasures, and eight member states signed a letter expressing their intention to sign the agreement. The aim of the agreement is to help member states to ensure that pandemic vaccines and medicines are available in sufficient quantities and at an advantageous price if a cross-border health threat arises.

The signatory states are Belgium, Czech Republic, Greece, Estonia, Spain, Croatia, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia and the United Kingdom. The member states which intend to sign the agreement are Germany, Ireland, France, Italy, Lithuania, Romania, Finland and Sweden.

Following the pandemic vaccines shortage in 2009 in the wake of the H1N1 swine flu, the Council and the European Parliament agreed on a legal basis for a joint procurement procedure for medical countermeasures, provided for by decision 1082/2013 on serious cross-border threats to health. The joint procurement agreement will enter into force 14 days after one third of the member states have ratified it (or have notified the Commission that they can approve it without a ratification procedure). Member states that have signed the agreement are not obliged to participate in the procurement of medical countermeasures.

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OTHER ITEMS APPROVED