



**COUNCIL OF  
THE EUROPEAN UNION**



11081/13

(OR. en)

PRESSE 263  
PR CO 33

## **PRESS RELEASE**

3247th Council meeting

### **Employment, Social Policy, Health and Consumer Affairs**

Luxembourg, 20 and 21 June 2013

Presidents      **Richard BRUTON**  
Minister for Jobs, Enterprise and Innovation of Ireland  
**Joan BURTON**  
Minister for Social Protection of Ireland  
**James REILLY**  
Minister for Health of Ireland

# **P R E S S**

---

Rue de la Loi 175 B – 1048 BRUSSELS Tel.: +32 (0)2 281 6319 / 6319 Fax: +32 (0)2 281 8026  
[press.office@consilium.europa.eu](mailto:press.office@consilium.europa.eu) <http://www.consilium.europa.eu/press>

11081/13

1  
**EN**

## **Main results of the Council**

### **Employment and Social Policy**

*The Council held a policy debate on the **European Semester 2013** in the field of employment and social policy.*

*It discussed **youth employment** in preparation for the forthcoming European Council's debate.*

*The Council agreed on a general approach on the **European globalisation adjustment fund** regulation, which allows for the start of negotiations with the European Parliament. It also reached a general approach on the proposed **supplementary pension rights** directive.*

*It took note of progress reports on the **posting of workers** directive and on a regulation on a **fund for European aid to the most deprived**.*

*Ministers took stock of progress reports on a proposed directive improving the **gender balance** among non-executive directors of companies listed on stock exchange, and on a proposed directive on **equal treatment**.*

*The Council adopted conclusions on : "Towards social investment for growth and cohesion", and "Women and the media: Advancing their roles as decision-makers".*

*It adopted without discussion:*

*- new rules **on capital requirements for banks and investment firms**. The proposals amend and replace existing capital requirement directives by two new legislative instruments: a regulation establishing prudential requirements that institutions need to respect, and a directive governing access to deposit-taking activities, and*

*- a directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from **electromagnetic fields***

*- new transparency rules for the extractive industry and simplification of accounting requirements for companies.*

### **Health and Consumer Affairs**

*The Council agreed a general approach on a revised draft **EU tobacco directive**, aimed at making tobacco products less attractive by strengthening rules on how tobacco products can be manufactured, presented and sold.*

*It also took note of presidency progress reports on a draft regulation concerning **clinical trials of medicines** and on two draft regulations concerning **medical devices**.*

**CONTENTS**<sup>1</sup>

|  |          |
|--|----------|
| <b>PARTICIPANTS.....</b>   | <b>5</b> |
| <b>ITEMS DEBATED</b>   |          |
| EMPLOYMENT AND SOCIAL POLICY .....   | 8        |
| European Semester 2013.....  | 8        |
| Youth employment.....  | 9        |
| Posting of workers .....   | 11       |
| Supplementary pension rights.....  | 12       |
| Fund for European aid to the most deprived (FEAD).....                                   | 13       |
| Social investment for growth and cohesion .....  | 14       |
| European globalisation adjustment fund (2014-2020).....                                  | 15       |
| Gender balance among non-executive directors of companies listed on stock exchanges..... | 16       |
| Equal treatment .....  | 17       |
| Women and the media.....   | 18       |
| Any Other Business .....   | 19       |
| HEALTH AND CONSUMER AFFAIRS .....  | 20       |
| Tobacco directive.....   | 20       |
| Clinical trials on medicines.....  | 22       |
| Medical devices.....   | 24       |
| Any Other Business .....   | 26       |

<sup>1</sup>

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

**OTHER ITEMS APPROVED***ECONOMIC AND FINANCIAL AFFAIRS*

- Bank capital requirements ..... 28

*JUSTICE AND HOME AFFAIRS*

- Common European Asylum System - Eurodac ..... 28
- Schengen Borders Code ..... 29

*EMPLOYMENT*

- Directive on electromagnetic fields ..... 29
- Conventions on chemicals at work and on decent work for domestic workers ..... 29

*SOCIAL POLICY*

- European Court of Auditors' report ..... 30

*INTERNAL MARKET*

- Motor vehicles - International harmonised requirements ..... 30

*COMPANY LAW*

- New transparency rules for the extractive industry and simplification of accounting requirements for companies ..... 30

*ENVIRONMENT*

- Interoperability of spatial data sets and services ..... 31
- EU Ecolabel ..... 32

*TELECOMMUNICATIONS*

- Re-use of public sector information ..... 32

## PARTICIPANTS

The governments of the member states and the European Commission were represented as follows:

### Belgium:

Ms Laurette ONKELINX

Deputy Prime Minister and Minister for Social Affairs and Public Health, with responsibility for Beliris and Federal Cultural Institutions

Ms Monica DE CONINCK  
Mr Philippe COURARD

Minister for Employment  
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 Tanya ANDREEVA-RAYNOVA  
Mr Hasan ADEMOV

Minister for Health  
Minister for Labour and Social Policy

### Czech Republic:

Mr Jan DOBEŠ  
Ms Jaroslava BENEŠ ŠPALKOVÁ

Deputy Minister for Labour and Social Affairs  
Deputy Minister for Common Agriculture and Fisheries Policies

### Denmark:

Ms Mette FREDERIKSEN  
Ms Astrid KRAG KRISTENSEN

Minister for Employment  
Minister for Health and Prevention

### Germany:

Ms Ursula VON DER LEYEN  
Mr Robert KLOOS\*

Federal Minister for Labour and Social Affairs  
State Secretary, Federal Ministry of Food, Agriculture and Consumer Protection  
Deputy Permanent Representative

Mr Guido PERRUZO

### Estonia:

Mr Taavi RÕIVAS

Minister for Social Affairs

### Ireland:

Mr Richard BRUTON  
Ms Joan BURTON  
Mr James REILLY

Minister for Jobs, Enterprise and Innovation  
Minister for Social Protection  
Minister for Health

### Greece:

Mr Ioannis VROUTSIS  
Mr Andreas LYKOURTOS

Minister for Employment, Social Protection and Welfare  
Minister for Health

### Spain:

Ms María Fátima BÁÑEZ GARCÍA  
Ms Pilar FARJAS  
Mr Joaquin GARCIA MARTINEZ

Minister for Employment and Social Security  
State Secretary for Health and Consumer Affairs  
Conseiller à l'Economie et à la Compétitivité, Communauté Autonome des Iles Baléares

### France:

Ms Marie-Arlette CARLOTTI

Minister with responsibility for the Disability and Social Exclusion Issues, attached to the Minister for Social Affairs and Health

Mr Alexis DUTERTRE

Deputy Permanent Representative

### Italy:

Mr Enrico GIOVANNINI  
Ms Beatrice LORENZIN

Minister for Labour and Social Policy  
Minister for Health

### Cyprus:

Mr Petros PETRIDES  
Mr George PAPAGEORGIOU

Minister for Health  
Permanent Secretary, Ministry of Labour and Social Insurance

**Latvia:**

Ms Ilze VIŅĶELE  
Ms Ingrīda CIRCENE

Minister for Welfare  
Minister for Health

**Lithuania:**

Ms Algimanta PABEDINSKIENĖ  
Mr Vytenis Povilas ANDRIUKAITIS

Minister for Social Security and Labour  
Minister for Health

**Luxembourg:**

Mr Nicolas SCHMIT  
Mr Mars DI BARTOLOMEO

Minister for Labour, Employment and Immigration  
Minister for Health, Minister for Social Security

**Hungary:**

Mr András DONCSEV  
Mr Miklós SZÓCSKA

State Secretary for Parliamentary Affairs  
State Secretary for Healthcare, Ministry of Human Resources  
Deputy Permanent Representative

Mr Olivér VÁRHELYI

**Malta:**

Mr Evarist BARTOLO  
Mr Godfrey FARRUGIA

Minister for Education and Employment  
Minister for Health

**Netherlands:**

Mr Lodewijk ASSCHER

Vice Prime Minister, Minister of Social affairs and Employment  
Deputy Permanent Representative

Mr Wepke KINGMA

**Austria:**

Mr Harald GÜNTHER

Deputy Permanent Representative

**Poland:**

Mr Bartosz ARLUKOWICZ  
Ms Malgorzata MARCINSKA

Minister for Health  
Undersecretary of State, Ministry of Labour and Social Policy

**Portugal:**

Mr Fernando LEAL da COSTA  
Mr Pedro ROQUE OLIVEIRA

State Secretary attached to the Minister for Health  
State Secretary for Employment

**Romania:**

Ms Mariana CÂMPEANU  
Mr Eugen Gheorghe NICOLĂESCU

Minister for Labour, the Family and Social Protection  
Minister for Health

**Slovenia:**

Ms Anja KOPAČ MRAK

Minister for Labour, the Family, Social Affairs and Equal Opportunities  
Minister of Health

Mr Tomaž GANTAR

**Slovakia:**

Ms Zuzana ZVOLENSKA  
Mr Branislav ONDRUŠ

Minister of Health  
State Secretary at the Ministry of Labour, Social Affairs and the Family

**Finland:**

Ms Lauri IHALAINEN  
Ms Susanna HUOVINEN  
Ms Marianne HUUSKO-LAMPONEN

Minister for Labour  
Minister for Health and Social Services  
Deputy Permanent Representative

**Sweden:**

Ms Hillevi ENGSTRÖM  
Ms Maria LARSSON

Minister for Employment  
Minister for Children and the Elderly

**United Kingdom:**

Ms Anna SOUBRY  
Mr Mark HOBAN

Minister for Health  
Minister of State for Employment

**Commission:**

Ms Viviane REDING  
Mr Joe BORG  
Mr László ANDOR

Vice-President  
Member  
Member

.....

The Government of the Acceding State was represented as follows:

**Croatia:**

Ms Milanka OPAČIĆ  
  
Mr Rajko OSTOJIĆ  
Mr Mirando MRSIĆ

Deputy Prime Minister and Minister for Social Policy and  
Youth  
Minister for the Interior  
Minister for Labour and Pension System

## **ITEMS DEBATED**

### **EMPLOYMENT AND SOCIAL POLICY**

#### **European Semester 2013**

The EPSCO Council held a policy debate (based on document [10367/13](#)) approving its contribution to the European Council regarding the employment/social policy aspects of the country-specific recommendations (CSRs) and the results of the multilateral surveillance.

In general, ministers welcomed the progress in the 2013 Semester exercise. There was overall greater satisfaction with the procedures, with member states pointing particularly to an amelioration of the political dialogue with the Commission in their bilateral meetings. The contribution of the EMCO and SPC committees in the process, as well as their coordination with the ECOFIN committees on cross-cutting issues, were widely welcomed. Room for improvement was generally recognised as well.

Most ministers underlined the importance of the involvement of social partners and the civil society in the CSRs process in order to ensure broader social acceptance of the reforms. They called for recognition of the efforts already undertaken at national level and for respecting the need to leaving discretionary scope for member states to implement reforms that aim for agreed outcomes.

The process of reforms to restore competitiveness and get public finances under control takes place in a context of protracted recession, high unemployment levels, most particularly for the young, and rising poverty and inequalities.

The challenges the Union is facing in finding a more sustainable growth path are complex and require a comprehensive and balanced policy mix. Conditions need to be put in place that will, at the same time, favour investment by companies and create employment, improve the efficiency of public expenditure and ensure the effectiveness of welfare systems.

The scale of the challenges, as well as the time needed for the positive effects of reforms to show results, nonetheless makes it essential to tackle them effectively and urgently.

The Council endorsed the opinions of the Employment Committee (EMCO) ([10397/13](#)) and of the Social Protection Committee (SPC) ([10222/13](#)) on the national reform programmes (2013) and the implementation of the 2012 country-specific recommendations. It took note of reports of the EMCO and SPC regarding the 2013 package of CSR's on cross-cutting issues. Additionally, it endorsed the employment performance monitor and benchmarks ([10373/13](#)).



## **Youth employment**

The Council discussed youth employment to provide input for the discussion of the Heads of State and government on 28-29 June ([10375/13](#) + [COR 1](#) + [COR 2](#)).

The Council discussed the extremely high unemployment rate of young people in a number of member states that has to be addressed. The crisis has hit across all layers of society and young people became one of the most affected groups. The situation is particularly acute in certain member states and regional differences in the youth unemployment rate are significantly increasing.

Over the recent time, the EU and member states have launched a series of initiatives and proposals to address the increasing unemployment rates for youth. However, youth unemployment continues to present a major challenge for the EU and for most member states. In April 2013, the youth unemployment rate reached 23.5% in the EU 27. Moreover, the disparities between regions within member states are significant: the youth unemployment rate is over 50% in some member states and over 70% in some regions, while in a few regions it is even below 5%. All in all, currently more than 7.5 million of young people under 25 are neither in employment, education or training (NEET).

Ministers pointed out that it is time now to move from words to action. They urged for accelerating the implementation of initiatives adopted with the aim of increasing the youth employment rate, and in particular of the recommendation on the Youth guarantee, in order to be able to use as quickly as possible the 6 billion EUR which the European Council has set aside for the Youth Employment Initiative for the next seven years. The ministers agreed that a firm commitment by the member states is needed to adopt concrete plans for the implementation of the guarantee at national level by the end of 2013 so that the funding can be available already from January 2014.

In order for the measures to be more effective, the ministers supported frontloading the funds of 6 billion EUR to achieve the maximum impact in the early years of the next Multiannual Financial Framework period. For this to happen, quick finalisation of the programming of the European Social Fund is crucial.

The ministers also highlighted the need of creating more jobs and the great potential of SMEs across Europe in this respect. In this context, the involvement of the European Investment Bank could be explored. The ministers also recognised the need to address the mismatches between demand and supply in some sectors of economy and to tackle the labour market segmentation. Young people have a high propensity to be mobile and the potential of targeted mobility schemes, such as "Your first EURES Job" should be therefore explored.

Finally, the ministers highlighted the importance of interconnecting the worlds of education and work and in particular the need for improving the traineeship and apprenticeship offers for young people and providing information on their carrier prospects based on the labour market situation. The social partners and public employment services have an important role to play in this process.

The Commission presented its communication on Youth Employment. This new communication should cover the following topics:

- the implementation of the Youth Guarantee;
- investment in young people through the European Social Fund;
- the front-loading of the Youth Employment Initiative;
- support for intra-EU labour mobility with EURES;
- steps to ease the transition from education to work by boosting the supply of high-quality apprenticeships and traineeships and addressing skills shortages;
- acceleration of reforms to deliver a genuine EU labour market in the longer run; and
- measures to support job creation in the immediate term, especially by SMEs, and to incentivise the hiring of young people.

## **Posting of workers**

The Council took note of a progress report regarding enforcement of the directive on posting of workers in the framework of the provision of services ([10430/13](#)).

The presidency's progress report notes that a possible way forward could be found by ensuring that Article 9 (national administrative requirements and control measures) contains some degree of flexibility. Such flexibility would involve incorporating existing national administrative requirements and control measures in the exhaustive list, while subjecting them to transparency requirements. In addition, a notification procedure would apply to new administrative and control measures with a view to ensure that they are compatible with Union law.

The proposed enforcement directive aims to provide posted workers with the minimum protection provided for in the posting of workers directive. It contains a long list of measures, including awareness raising (better information), state enforcement mechanisms (inspections and sanctions) and private law enforcement mechanisms (joint and several liability).

### **Supplementary pension rights**

The Council reached a general approach on a proposed directive improving the acquisition and preservation of supplementary pension rights ([10890/13](#) + [ADD1](#) + [ADD 2](#)).

The Commission proposal dating back to 2005 has grown in importance: supplementary pensions are becoming more significant and there is a need to facilitate worker mobility. Following the European Parliament's opinion in 2007, the Commission adopted an amended proposal which excludes the issue of transferability of pension rights.

In 2012, the European Council called for the sustainability of pension systems to be improved and for the acquisition and preservation of supplementary pension rights of mobile workers to be strengthened.

The Irish presidency tabled a compromise suggestion, restricting the scope of the directive to cases of mobility between member states only.

The compromise suggestion would leave the member states free to decide on the rules they apply to internally mobile workers. However, the Council and the Commission made a statement encouraging the member states to ensure the equal treatment of internally and externally mobile workers.

Statutory social security pensions (so-called 'pillar I' pensions) earned in different member states are co-ordinated under regulation 883/2004/EC, which ensures that if a person works in more than one member state they do not lose out when it comes to their statutory social security pension entitlements. Occupational pensions (so-called 'pillar II' pensions) enjoy limited protection under Council directive 98/49/EC, with respect to the preservation of pension rights.

The proposal under discussion aims to strengthen the protection of occupational pensions.

### **Fund for European aid to the most deprived (FEAD)**

The Council took stock of the progress made on the proposal on the Fund for the most deprived regulation ([10896/13](#)), submitted by the Commission in October 2012.

In February 2013, the European Council confirmed that the support for aid for most deprived people will be EUR 2.5 billion for the period 2014-2020 and will be taken from the ESF allocation.

Substantial progress has been achieved under the Irish presidency on many parts of the text. More particularly, the discussions have shown broad support to the objectives of the Fund, with a majority of delegations also supporting the instrument itself while, at the same time, some delegations maintain reservations on the new Fund (whether a new EU-level Fund, covering all member states, would be the most appropriate way of assisting the most deprived persons, and what form such a fund should take).

Delegations have also discussed in detail how the Fund's management should be organised, so that it would not create unnecessary duplication and administrative burden to the member states and to the partner organisations working with the most deprived persons.

The EP Plenary has only voted its mandate on 12 June. The Council will further examine the text, including the EP's opinion.

The general objective of the proposed instrument, which is expected to be operational on 1 January 2014, is to promote social cohesion by contributing to achieving the EU2020 poverty reduction headline target. More specifically, the instrument will aim to alleviate the worst forms of poverty by providing non-financial assistance to the most deprived people.

The proposed budget is 2.5 billion euros over the period 2014 to 2020 under the heading of the cohesion policy budget. The Fund would support schemes in member states providing food to the most deprived people as well as basic goods such as clothing and other essential goods to homeless people and materially-deprived children.

## **Social investment for growth and cohesion**

The Council adopted conclusions ([11487/13](#)) following Commission's communication "Towards social investment for growth and cohesion" presented in February this year.

The so called Social Investment Package (SIP) is a new policy framework that should give a fresh impetus to achieving the overall Europe 2020 target of reducing the number of people at risk of poverty by 20 million and fighting social exclusion, progress having stalled in the last two years. According to the Commission, the package should demonstrate that, despite the current budgetary constraints, better social outcomes can be achieved, without necessarily spending more.

The conclusions stress that finding a longer-term exit from the crisis in terms of poverty and social exclusion would be difficult without well-designed and effective reforms at national level. These reforms should aim at strengthening human capital, health, education and skills, fostering social inclusion and participation. Improving the effectiveness and efficiency of social protection systems is a central goal.

The conclusions also highlight the usefulness of the European Semester and the open method of coordination in this respect, and in particular mutual learning and sharing experiences and good practices in the future.

Finally, the conclusions welcome in particular the recommendation on child poverty which is a part of the package and which calls for preventative and child-friendly approach to social investment. Providing access to adequate resources and good quality and affordable services is crucial for breaking the vicious circle of transmission of disadvantage across generations.

**European globalisation adjustment fund (2014-2020)**

The Council agreed on a general approach on the European globalisation adjustment fund regulation, which allows for the start of negotiations with the European Parliament. Ministers discussed the presidency compromise proposal amended by a (joint Franco-German) proposal strengthening the support to unemployed people between the age of 15-24 years in regions of high youth unemployment rates.

## **Gender balance among non-executive directors of companies listed on stock exchanges**

The Council took note of a progress report ([10422/1/13](#)) on a directive which would improve the gender balance on company boards.

Aiming to address the problem of women's under-representation in economic decision-making at the highest level, the directive would set a quantitative objective for the proportion of the under-represented sex on the boards of listed companies of 40% by 2020 (by 2018 in the case of public undertakings). The companies would be obliged to work towards that objective, inter alia, by introducing procedural rules on the selection and appointment of non-executive board members. Should companies fail to reach the 40% target by the deadline set, they would be required to continue to apply the procedural rules, as well as to explain what measures they had taken and intended to take in order to reach it. Companies would face sanctions only for failing to implement those procedural obligations. For member states that choose to apply the objective to both executive and non-executive directors, a lower target (33%) would apply.

Some parliaments have submitted reasoned opinions within eight weeks from the submission of the Commission's proposal, alleging that it did not comply with the principle of subsidiarity.

During the examination of the directive under the Irish presidency significant progress has been made. It appeared that while all delegations were in principle in favour of improving gender balance on company boards, some prefer national measures while others support EU-wide legislation. Accordingly, more work will be needed to clarify and amend aspects of the Commission proposals before a compromise can be reached.

Women account for around 60 % of new university graduates in the EU, yet are under-represented in economic decision-making positions, especially at the top. The situation is improving, albeit slowly, thanks to measures being taken nationally as well as to the intensifying public debate on this issue.

According to the Commission, in October 2012, only around 15.8% of board members and just 3% of board chairs of the largest companies listed on the stock exchanges of the EU member states were women.



## **Equal treatment**

The Council took note of a progress report ([10039/13](#)) on the proposed equal treatment directive that would prohibit discrimination on the grounds of religion or belief, disability, age or sexual orientation in the following areas: social protection, including social security and healthcare; social advantages; education; and access to goods and services, including housing. The Irish presidency focussed in particular on the scope of the directive and on the issue of disability.

A large majority of delegations welcomed the proposal submitted to the Council in 2008, considering that it completes the existing legal framework by addressing the before-mentioned four grounds of discrimination through a horizontal approach.

As the proposal falls under article 19 of the Treaty on the functioning of the EU, unanimity in the Council is required, following the consent of the European Parliament.

## **Women and the media**

The Council adopted conclusions ([10665/13](#)) concerning women and the media, with a specific focus on the role that women play in decision-making.

These conclusions are based on a report prepared by the European Institute for gender equality ([10366/13 ADD 1](#)). The report shows that persistent gender inequalities in the media can be challenged by advancing women in decision-making.

Therefore, the present conclusions make an appeal for active and specific measures to foster gender equality at all levels in this important sector. They also include a set of three indicators for measuring progress on this issue. The first two indicators track the proportion of women and men in decision-making positions in media organisations and in boardrooms. The third indicator monitors the policies that media organisations have put in place to promote gender equality.

**Any Other Business**

- Proposal for a decision of the European Parliament and of the Council on public employment services and the functioning of the European labour market

The Council took note of the information given by the Commission.

- Legislative files and other issues

The presidency informed the Council on the state of play of various legislative dossiers.

- G20 labour and employment ministers' meeting and joint meeting with finance ministers (Moscow, Russia, 18-19 July 2013)

The Council took note of the information given by the presidency and the Commission on the upcoming G20 ministerial meetings.

- Conferences organised by the Irish presidency.

The presidency informed the delegations on the conferences organised during its term.

- Work programme of the incoming presidency

The Lithuanian delegation informed the Council about its work programme.

## HEALTH AND CONSUMER AFFAIRS

### Tobacco directive

The Council agreed a general approach<sup>1</sup> on a revised draft EU tobacco directive aimed at making tobacco products less attractive by strengthening the rules on how tobacco products can be manufactured, presented and sold ([11483/13](#)).

The deal, which was reached on the basis of a compromise proposal from the Irish presidency, includes the following key elements:

- A **ban** on the use of cigarettes and roll-your-own tobacco with **characterising flavours** such as fruit flavours, chocolate or menthol or which contain additives that increase addictiveness and toxicity. This is to make sure that tobacco products taste and smell like tobacco products.
- An obligation for **combined picture and text health warnings to cover 65 %** of the front and the back of packages of tobacco products for smoking.
- A **ban** of any **misleading labelling** (such as "natural" or "organic").
- The **extension of the scope** of the directive to
  - **novel tobacco products** (products that are placed on the market after the entry into force of the directive) which would require a prior notification before being placed on the market;
  - **nicotine containing products** (such as electronic cigarettes); these products would be allowed on the market below a certain nicotine threshold provided they feature health warnings; above this threshold such products would only be allowed if authorised as medicinal products (e.g. nicotine replacement therapies);
  - **herbal products for smoking** which would have to carry health warnings.

---

<sup>1</sup> A general approach is a political agreement of the Council pending the first-reading position of the European Parliament.

- Introduction of a **tracking and tracing system**, together with safety features in order to strengthen the fight against illicit trade and falsified products;
- Member states may decide to ban **cross-border distance sales** of tobacco products;
- Member states may introduce more stringent rules on additives or on packaging of tobacco products (such as **plain-packaging**), subject to certain conditions (such as notification of the Commission).

The general approach agreed today enables the incoming Lithuanian presidency to engage discussions with the European Parliament on this file. The committee for environment, public health and food safety of the European Parliament is expected to vote its draft amendments in July.

## Clinical trials on medicines

The Council took note of a presidency progress report on a draft regulation concerning clinical trials on medicines for human use ([10452/13](#)).

The Commission proposal published on 17 July 2012 ([12751/12](#)) is aimed at speeding up the authorisation of investigations of medicines in humans where patients are recruited in more than one member state while maintaining the high standards of patient safety.

Medicines are clinically tested in human volunteers to

- test the safety and effectiveness of new products,
- test new applications for existing medicines or to
- compare two treatments.

Clinical trials are hence essential to develop new medicines and to improve medicinal treatment. The data generated in clinical trials are published in medical journals and can be used by companies applying for marketing authorisations.

The Commission proposed to:

- set up a **simplified authorisation procedure** with a swift assessment by all member states in which the clinical trials are intended to be conducted;
- make a distinction between aspects where member states must cooperate in the assessment and those where member states conduct their assessment individually (such for instance on ethical aspects);
- to ensure that the principle of **risk-proportionality** is applied, for instance on the compensation for damages;

- replace the current directive by a regulation in order to **ensure a uniform application of common rules.**<sup>1</sup>

During its first read-through of the proposal the Council's working party on pharmaceuticals and medical devices identified a number of elements on which further discussion is needed, notably:

- the shortening of time-limits for the authorisation and validation of clinical trials;
- the ethical evaluation of clinical trials;
- the protection of volunteers;
- the damage compensation and indemnification mechanism.

---

<sup>1</sup> Due among others to a divergent transposition of the current clinical trials directive the clinical trial activity has considerably decreased in the EU in the last years. The number of applications for clinical trials fell by 25% from 2007 to 2011 (from 5000 to 3800).

## Medical devices

The Council took note of a presidency progress report on two draft regulations concerning medical devices and in vitro diagnostic medical devices ([11051/13](#)).

Medical devices cover a huge spectrum of products and include for instance sticking plasters, corrective glasses, dental filling material, X-ray machines, bone screws, heart valves and breast implants. Likewise, there is a wide range of in vitro diagnostic medical devices which include for instance blood tests and other products used for disease prevention, diagnosis, monitoring of prescribed treatments and assessment of medical interventions.

The Commission proposals, presented on 26 September 2012 ([14493/12](#) + [14499/12](#)), are aimed at strengthening transparency on the available medical devices and in vitro diagnostic medical devices, increasing their traceability, beefing up market surveillance and reinforcing the powers of so-called notified bodies.

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 of 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 proposal contains the following key elements:

- **Patients** who are implanted with a device should 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.
- Manufacturers of medical devices and in vitro diagnostic medical devices 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**.
- Manufacturers of high-risk devices and diagnostic devices must make publicly available a **summary of their safety and performance**, with key elements of the clinical data.
- Introduction of an **EU portal where manufacturers must report serious incidents** and corrective actions they have taken to reduce the risk of recurrence.



- Notified bodies have the right and duty to carry out **unannounced factory inspections** and to conduct physical or laboratory tests on devices and diagnostic devices.
- 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 the predisposition to a disease.
- The two existing directives are replaced by two regulations in order to ensure that the EU rules are applied in the same manner in all member states

In its examination of the proposals the Council's working party on pharmaceuticals and medical devices has so far identified the following main difficulties:

- the procedures for clinical evaluation;
- the method for strengthened control by notified bodies.

## **Any Other Business**

### ***Serious cross-border health threats***

The presidency informed the Council on the agreement on the draft decision on serious cross-border threats to health reached at the trilogue discussions with representatives of the European Parliament and the Commission on 6 May 2013. The agreement is expected to be formally voted by the European Parliament in September, after which it will be formally approved by the Council. This would allow the decision to enter into force before the end of the year ([10332/13](#)).

For details on the content of the agreement see [9610/13](#).

### ***Coronavirus***

The Council took note of the information provided by the Commission on the middle East respiratory syndrome coronavirus several cases of which were also identified within the EU (United Kingdom, Germany, France and Italy) ([11000/13](#)).

### ***Drugs action plan***

The presidency informed the Council about the EU action plan on drugs for 2013-2016 adopted by the Justice and Home Affairs Council at its meeting on 6-7 June 2013 ([10448/13](#)). The EU action plan on drugs focuses on the two policy areas of drug demand reduction and drug supply reduction, and three cross cutting themes - coordination, international cooperation and information, research, monitoring and evaluation.

### ***Patient's rights in cross-border healthcare***

The Council took note of information provided by the Commission on the state of play in the transposition of the directive into national law ([10363/13](#)). Directive 2011/24 on the application of patients' rights in cross-border healthcare is due to be transposed by the member states by 25 October 2013. The Commission services have carried out a programme of visits to member states to assist in transposition of the directive.

***Transparency of prices of medicinal products***

The presidency informed the Council on the progress achieved on the amended Commission proposal ([10365/13](#)). The Commission proposed inter alia new time lines for decisions in order to guarantee a transparent and equal treatment of manufacturers of medicinal products applying for the inclusion of a product in national health insurance system of member states.

***Imports of active pharmaceutical ingredients***

The Council took note of a Commission report concerning the import of active pharmaceutical ingredients within the context of the entry into application of new provisions on this issue as part of directive 2011/62 on falsified medicines ([10364/13](#)).

***Work programme of the forthcoming presidency***

The Lithuanian 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 adopted new rules on capital requirements for banks and investment firms ([14/13](#) and [15/13](#)). The decision was taken by a qualified majority of delegations, with the United Kingdom voting against ([10851/13](#) + [10853/13](#)).

Adoption of the "CRD4" legislation follows agreement reached with the European Parliament at first reading on 28 February, and subsequent approval by the Permanent Representatives Committee, on behalf of the Council, on 27 March.

The proposals amend and replace existing capital requirement directives<sup>1</sup> by two new legislative instruments: a *regulation* establishing prudential requirements that institutions need to respect, and a *directive* governing access to deposit-taking activities.

For details see [11290/13](#).

### **JUSTICE AND HOME AFFAIRS**

#### **Common European Asylum System - Eurodac**

The Council adopted the last piece of legislation needed to complete the Common European Asylum System (CEAS), namely the amended Eurodac regulation ([PE-CONS 17/13](#)).

For more information see [11160/13](#).

---

<sup>1</sup> Directives 2006/48/EC and 2006/49/EC

## **Schengen Borders Code**

The Council adopted a number of amendments to regulation (EC) No 562/2006 establishing a Community Code on the rules governing the movement of persons across borders (**Schengen Borders Code**) and a number of consequential amendments to related provisions in other instruments such as the Schengen Convention ([PE-CONS 3/13](#)).

For more information see [11300/13](#).

## **EMPLOYMENT**

### **Directive on electromagnetic fields**

The Council adopted a directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields ([10700/13](#)).

This directive is to replace a 2004 directive which has never entered into force because of problems with its implementation. It reviews exposure limitations on the basis of new scientific evidence and provides for derogations, in particular for medical applications using magnetic resonance imaging.

### **Conventions on chemicals at work and on decent work for domestic workers**

The Council reached a general approach for Council decisions authorising member states to ratify, in the interests of the EU:

- the 1990 Convention concerning safety in the use of chemicals at work, of the International Labour Organization (Convention No 170), and
- the 2011 Convention concerning decent work for domestic workers, of the International Labour Organisation (Convention No 189).

## **SOCIAL POLICY**

### **European Court of Auditors' report**

The Council adopted conclusions on following European Court of Auditors' report: "Are tools in place to monitor the effectiveness of European Social Fund spending on older workers?" ([10095/13](#)).

## **INTERNAL MARKET**

### **Motor vehicles - International harmonised requirements**

The Council adopted a decision on the EU's position, to be taken within the United Nations Economic Commission for Europe (UNECE), with a view to adapting to technical progress regulations Nos 13, 13H, 16, 29, 44, 53, 79, 94, 95, 96, 117 and 130, as well as adopting a proposal for a UNECE global technical regulation on hydrogen and fuel cell vehicles and the adaptation of regulations Nos 2 and 12 ([10157/13](#)).

The UNECE develops international harmonised requirements intended to remove technical barriers to the trade in motor vehicles.

## **COMPANY LAW**

### **New transparency rules for the extractive industry and simplification of accounting requirements for companies**

The Council adopted a directive for the review of the accounting rules applicable to EU companies ([PE-CONS 20/13](#)).

The Estonian and Hungarian delegations voted against and the Portuguese, Spanish and Bulgarian delegations abstained ([10703/13 ADD1](#)).

The key objectives of the review are:

- to reduce administrative burdens and to simplify accounting rules, particularly for small and medium-sized enterprises;

- to increase the clarity and comparability of financial statements; and
- to enhance transparency on payments made to governments by the extractive industry and loggers of primary forest.

The new rules will impose an obligation to report on payments made by the extractive industry and loggers of primary forest to governments in third countries (also referred to as country-by-country reporting).

Large undertakings and public-interest entities which are active in the extractive industry or logging of primary forests shall disclose payments made to governments in the countries in which they operate if the total amount of payments exceeds EUR 100 000 per year. Such undertakings normally operate in countries rich in natural resources, in particular minerals, oil, natural gas as well as primary forests.

*For more information see press release [8530/13](#).*

## **ENVIRONMENT**

### **Interoperability of spatial data sets and services**

The Council decided not to oppose the adoption of a Commission's regulation amending regulation (EU) No 1089/2010 implementing directive 2007/2/EC as regards interoperability of spatial data sets and services ([8982/13](#), [8982/13 ADD1](#)).

The Commission regulation is subject to the so called regulatory procedure with scrutiny. This means that now that the Council has given its consent, the Commission may adopt the regulation, unless the European Parliament objects.

## **EU Ecolabel**

The Council decided not to oppose the adoption of a Commission's regulation amending annex III to regulation (EC) No 66/2010 of the European Parliament and of the Council on the EU Ecolabel ([9400/13](#)).

The Commission regulation is subject to the so called regulatory procedure with scrutiny. This means that now that the Council has given its consent, the Commission may adopt the regulation, unless the European Parliament objects.

## **TELECOMMUNICATIONS**

### **Re-use of public sector information**

The Council adopted a revision of the 2003 directive on re-use of data produced and collected by public bodies, also called public sector information (PSI) ([PE-CONS 18/13](#)), following the approval given by the European Parliament on 13 June.

The objective of the new directive, which forms part of the [Digital Agenda for Europe](#) and the Europe 2020 strategy for smart, sustainable and inclusive growth, is to eliminate differences between member states in the exploitation of public sector information which hamper attainment of the full economic potential of this resource. In doing so, the revision aims to facilitate the creation of Union-wide products and services based on PSI and to ensure the effective cross-border use of PSI.

The revision extends the directive's scope to cover certain cultural institutions, namely museums, libraries and archives. Moreover, member states will have the obligation to allow the re-use of existing generally accessible documents held by public sector bodies. Finally, the new directive establishes rules on charging for re-use of public service information.

Public sector information is the single largest source of information in Europe. It includes digital maps, meteorological, legal, traffic, financial, economic and other data. Most of this raw data could be re-used, that is, used for other purposes than the initial purpose, or integrated into new [products and services](#) which we use on a daily basis, such as car navigation systems, weather forecasts, financial and insurance services.