



Council of the  
European Union

Brussels, 5 December 2014  
(OR. en)

16258/14  
ADD 1

PV/CONS 63  
SOC 841  
EMPL 188  
SAN 461  
CONSOM 264

## DRAFT MINUTES

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Subject: **3351st** meeting of the COUNCIL OF THE EUROPEAN UNION  
(**EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER  
AFFAIRS**) held in Brussels on 1 December 2014

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## PUBLIC DELIBERATION ITEMS<sup>1</sup>

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### **LEGISLATIVE DELIBERATIONS**

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Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices [First reading]

### **NON LEGISLATIVE ACTIVITIES - PUBLIC DEBATE**

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<sup>1</sup> Deliberations on Union legislative acts (Article 16(8) of the Treaty on European Union), other deliberations open to the public and public debates (Article 8 of the Council's Rules of Procedure).

## **LEGISLATIVE DELIBERATIONS**

*(Public deliberation in accordance with Article 16(8) of the Treaty on European Union)*

### **"A" ITEMS**

**1. Proposal for a Regulation of the European Parliament and of the Council on reporting and transparency of securities financing transactions [First reading]**

= General approach

15897/14 EF 319 ECOFIN 1071 CODEC 2334

15424/14 EF 309 ECOFIN 1043 CODEC 2227

approved by Coreper, Part 2, on 20.11.2014

The Council confirmed the general approach with regard to the proposed Regulation, as set out in doc. 15424/14, and requested the Presidency to conduct negotiations with the European Parliament on the basis of the agreed general approach with a view to reaching an agreement at first reading.

### **"B" ITEMS**

**4. Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 [First reading]**

*(Legal basis proposed by the Commission: Articles 114 and 168(4)(c) TFEU)*

*Interinstitutional file: 2012/0266 (COD)*

and

**Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices [First reading]**

*(Legal basis proposed by the Commission: Articles 114 and 168(4)(c) TFEU)*

*Interinstitutional file: 2012/0267 (COD)*

– Progress report

14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305

+ COR 1

14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312

+ COR 1

16116/14 PHARM 97 SAN 454 MI 947 COMPET 651 CODEC 2369

The Council took note of the progress report as set out in the doc. 16116/14 and asked its preparatory bodies to continue the work with the goal of establishing a Council position, which should be a basis for negotiations with the European Parliament.

## NON LEGISLATIVE ACTIVITIES - PUBLIC DEBATE

*(Public debate in accordance with Article 8(2) of the Council's Rules of Procedure [proposed by the Presidency])*

### 5. Europe 2020 - Mid-term review

- Exchange of views

15480/14 SAN 431 PHARM 89 SOC 779 POLGEN 161 COMPET 622  
ECOFIN 1048

The Council held an exchange of views on the basis of the note submitted by the Presidency and questions contained therein.

The Council recognized that health sector makes an important contribution to economic growth and employment. A number of delegations called for better reflection of the role of good health of population in achieving the objectives of the EU 2020 strategy. It was stressed that the organisation and delivery of health services and medical care, which needs to be also respected in the European Semester process. The addition of specific headline target related to health was not supported and the best way forward could be the information and best practices exchange with the objectives to improve sustainability and efficiency of member states' health systems.

### 6. Draft Council conclusions on vaccination as an effective tool in public health

- Adoption

15090/14 SAN 418 PHARM 84  
+ REV 1 (hr)

The Council adopted the conclusions as set out in doc. 15090/14. The text will be published in the EU Official Journal.

### 7. Draft Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance

- Adoption

15441/14 SAN 429

The Council adopted the conclusions as set out in the doc. 15441/14. The text will be published in the EU Official Journal.

### 8. Draft Council conclusions on innovation for the benefit of patients

- Adoption

15838/14 PHARM 92 SAN 446 MI 922 COMPET 636

The Council adopted the conclusions as set out in the doc. 15838/14. The text will be published in the EU Official Journal.