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OUTCOME OF THE COUNCIL MEETING

3351st Council meeting

Employment, Social Policy, Health and Consumer Affairs

Health

Brussels, 1 December 2014

President **Beatrice Lorenzin**
Minister for Health of Italy

P R E S S

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Main results of the Council

Medical devices

The Council took note of a presidency progress report on two draft regulations concerning medical devices and in-vitro diagnostic medical devices.

"The substantial work done under the Italian presidency has been acknowledged by the Council", said Beatrice Lorenzin, the Italian Minister for Health and President of the Council, adding: "Our aim is to ensure the highest level of protection for European patients and to allow safe and innovative medical products and medical devices to be placed on the market rapidly. This is crucial for the well-being of European citizens and for the competitiveness of European industry."

Council conclusions

Ministers adopted conclusions on

- vaccination*
- patient safety and quality of care*
- innovation for the benefit of patients*

Ebola

The Commission updated the Council on the situation with regard to Ebola and ministers discussed the issue on this basis.

¹ • 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.

CONTENTS¹

PARTICIPANTS.....	5
--------------------------	----------

ITEMS DEBATED

Medical devices.....	7
Europe 2020 mid-term review	9
Vaccination	10
Patient safety.....	10
Innovation for the benefit of patients.....	10
Any other business	11
– Ebola	11
– Trafficking in human organs	11
– Admissibility criteria for homosexuals for blood donations.....	11
– Conferences.....	11
– Work programme of incoming presidency	11
In the margins of the Council.....	12
– Signing ceremony of the joint procurement agreement.....	12
– World AIDS day.....	12

OTHER ITEMS APPROVED*ENVIRONMENT*

– Convention on the Transboundary Effects of Industrial Accidents.....	13
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FOREIGN AFFAIRS

– Restrictive measures - Central African Republic	13
– Restrictive measures - Democratic Republic of Congo.....	13
– Action to combat nuclear weapons.....	13

COMMON SECURITY AND DEFENCE POLICY

- EU Operations Centre 14

ECONOMIC AND FINANCIAL AFFAIRS

- Securities financing transactions 14
- Short selling - Sovereign debt 14

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Ms Shan MORGAN

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Commission:

Mr Vytenis ANDRIUKAITIS

Member

ITEMS DEBATED

Medical devices

The Council took note of a presidency progress report on two draft regulations on medical devices and in vitro diagnostic medical devices ([15881/14](#)). It instructed its preparatory bodies to continue working on these files to establish a Council position.

Considerable progress has been achieved on these files under the Italian presidency has been achieved, enabling a better understanding of the whole package. However, further discussions are needed for the Council to agree its position. Outstanding issues include the aesthetics, reprocessing of single-use devices, the unique device identification system, notified bodies, clinical investigation, tasks of the proposed medical device coordination group, the role of expert panels and reference laboratories, the scrutiny mechanism for certain high-risk devices and post-market surveillance. The presidency's objective is to compile a text covering both proposals by the end of the year which could serve as a reference text for the incoming presidency.

The revision of the EU laws on medical devices is aimed at providing the highest level of protection for European patients, consumers and healthcare professionals, whilst ensuring 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 means all equipment used for medical purposes. They cover products as different as scissors, contact lenses, surgical tools, artificial heart valves, dialysis machines, breast implants and X-ray and scanner machines. There is also 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 ([14493/12](#) + [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, in the case of ***in vitro* diagnostic medical devices**, to tests providing information about the predisposition to a disease (e.g. **genetic tests**) for example

- economic operators must be able to identify who supplied medical devices and to whom they were supplied; 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 on which **manufacturers must report serious incidents** and corrective actions they have taken to reduce the risk of recurrence
- notified bodies get the right and duty to carry out **unannounced factory inspections** and to conduct physical or laboratory tests on medical devices and *in vitro* devices

Europe 2020 mid-term review

The Council exchanged views on the contribution that investments in health systems can make to the objectives of Europe 2020, the EU's growth strategy. It was guided by a presidency note set out in [15480/14](#).

Member states recognized that health is not only an important factor for social well-being but also makes an important contribution to economic growth and employment. A number of delegations called for deeper reflection on the role played by healthy population in achieving the objectives of the EU 2020 strategy and some of its headline targets (such as employment, research and education). The addition of specific headline target related to health was not supported. As the provision of healthcare and the organisation of health systems comes under the competence of the member states, the best way forward is to exchange information and best practices with a view to improving the sustainability and efficiency of member states' health systems. The cooperation between the Council working party on public health at senior level and the Social Protection Committee in assessing health-related country-specific recommendations under the European Semester process need to continue and to be further strengthened.

The review of the EU 2020 strategy is being addressed in all relevant Council configurations, with each focusing on aspects within its competence. The presidency intends to feed the outcome of the discussions on the various Council configurations into a summary report to be endorsed by the General Affairs Council of 16 December and forwarded to the European Council on 18-19 December. This summary will provide input to the Commission which is expected to present proposals in time for a discussion in the March 2015 European Council. The review of the strategy is due to be endorsed by the European Council in 2015.

Vaccination

The Council adopted conclusions on vaccinations as an effective tool in public health set out in [15090/14](#).

Patient safety

The Council adopted conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance, set out in [15441/14](#).

Innovation for the benefit of patients

The Council adopted conclusions on innovation for the benefit of the patients, set out in [15838/14](#).

The Council conclusions follow on from the debate at the informal meeting of ministers for health in Milan on 22-23 September, at which the ministers agreed that patients should benefit from new therapies at affordable prices and that innovation in the pharmaceutical sector needed to be supported.

Any other business– ***Ebola***

The Commissioner for Health and Food Safety, Vytenis Andriukaitis, updated the Council on the situation with regard to Ebola ([15979/14](#)). He stressed the urgent need to send more personnel to the field and reported on a number of important measures taken in recent weeks. These included (1) a joint mission of the Commission and the European Centre for Disease Prevention and Control (ECDC) in the affected countries which found that exit screening was been performed in line with the rules and that the risk of an infected person travelling outside the countries concerned was therefore very low; (2) the launch of an EU network of clinicians on 11 November, aimed at sharing good practices on treatment of Ebola patients; (3) a record of the fact that the EU coordination mechanism for Ebola patients' evacuation is now fully operative; (4) a survey conducted by ECDC showing that there is a sufficient high level of preparedness for management of viral haemorrhagic fevers patients including those suffering from Ebola in the EU member states.

– ***Trafficking in human organs***

The Spanish delegation called on member states and the EU to sign the convention against trafficking in human organs ([15513/14](#)).

– ***Admissibility criteria for homosexuals for blood donations***

With the support of the Dutch delegation the Luxembourg delegation will call upon the member states to ensure that exclusion from blood donation is linked to high-risk behaviour and not to sexual orientation ([15553/14](#)).

– ***Conferences***

The presidency informed the Council about the outcome of conferences held during its term of office ([16107/14](#)).

– ***Work programme of incoming presidency***

The Latvian delegation informed ministers about its work programme in the field of health and consumer affairs in its capacity as the incoming Presidency of the Council of the EU.

In the margins of the Council

– Signing ceremony of the joint procurement agreement

Denmark and Lithuania signed the joint procurement agreement for pandemic vaccines and other medical countermeasures, thereby bringing the number of signatories to 20. 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 in the event of the emergence of a cross-border health threat.

The signatory states are Denmark, Lithuania, Hungary, Italy, Romania, Luxembourg, Belgium, Croatia, the Czech Republic, Cyprus, Estonia, Greece, Latvia, Malta, the Netherlands, Portugal, Slovakia, Slovenia, Spain and the United Kingdom.

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 entered into force on 5 July 2014.

– World AIDS day

On the occasion of World AIDS day on 1 December the Presidency underlined the importance of this day and of the continued need to fight against this disease.

OTHER ITEMS APPROVED

ENVIRONMENT

Convention on the Transboundary Effects of Industrial Accidents

The Council adopted a decision on the position to be adopted, on behalf of the EU, at the eight Conference of the Parties to the Helsinki Convention on the Transboundary Effects of Industrial Accidents with regard to the proposal for an amendment to annex I ([15610/14](#)).

The Council also adopted a decision authorising the Commission to negotiate on the amendment of the Convention on the Transboundary Effects of Industrial Accidents ([15663/14](#)).

The eight meeting of the Conference of the Parties to the Convention will take place in Geneva, on 3-5 December 2014. For more information see the Convention [website](#).

FOREIGN AFFAIRS

Restrictive measures - Central African Republic

The Council amended the EU restrictive measures against the Central African Republic to take account of decisions at the UN. The Council updated information regarding three persons on the list of those targeted by the sanctions.

Restrictive measures - Democratic Republic of Congo

The Council amended the restrictive measures against the Democratic Republic of Congo to take account of changes decided by the UN. It added one entity to the list of those subject to the sanctions and updated information concerning other entries on that list.

Action to combat nuclear weapons

The Council approved a change to its decision granting support to the Comprehensive Nuclear-Test-Ban Treaty Organisation. It extended the period of validity of the funding decision by 12 months. This will enable the remaining parts of the projects to be implemented.

COMMON SECURITY AND DEFENCE POLICY

EU Operations Centre

The Council extended the activation of the EU Operations Centre until December 2016. The Operations Centre will have an expanded role concerning civil/military coordination and planning support. Besides working with the three CSDP actions in the Horn of Africa, it will now also assist the CSDP missions in the Sahel region: the EU training mission in Mali (EUTM) as well as EUCAP Sahel Niger and EUCAP Sahel Mali, which support the fight against terrorism and organised crime.

ECONOMIC AND FINANCIAL AFFAIRS

Securities financing transactions

The Council confirmed an agreement reached on a draft regulation aimed at improving the transparency of securities lending and repurchase transactions ([15897/14](#) + [15424/14](#)).

On 20 November 2014 the Permanent Representatives Committee agreed the Council's negotiating stance on the proposal, enabling negotiations with the European Parliament to start.

For details, see press release [15679/14](#).

Short selling - Sovereign debt

The Council decided not to object to the adoption by the Commission of a regulation on the notification of significant net short positions in sovereign debt ([14484/14](#) + [15708/14](#)).

The regulation, a delegated act, can now be published and enter into force, unless the European Parliament objects.
