

# HEALTH AND CONSUMER VOICE

## Patient safety: EU proposes tighter rules for medical devices



EU Commissioner for Health and Consumer Policy, John Dalli: «The safety of patients and consumers is a fundamental concern.»

Two new proposals to boost safety, efficiency and innovation in medical devices and *in vitro* diagnostic devices were adopted by the European Commission on 26 September. They will increase patient safety and make the legal framework for medical devices stronger, more transparent and better adapted to scientific and technological progress.

Referring to the recent scandal involving fraudulent breast implants which affected tens of thousands of women in the EU, Commissio-

ner for Health and Consumer Policy, John Dalli, said the new proposals would “ensure that only safe devices are placed on the European Union’s market”.

At the same time, they will foster innovation and maintain the competitiveness of the EU’s medical device sector which currently has an estimated market value of around €95 billion.

### What is a medical device?

Plasters, breast implants, glasses, pacemakers, X-ray machines...a medical device is an instrument, apparatus, implant, or similar device used for the diagnosis, treatment, cure or prevention of disease or other conditions. *In vitro* medical devices include diagnostic tests e.g. blood tests for cholesterol & HIV and home pregnancy tests. There are around 500 000 different medical devices on the EU market.

### The proposals include:

- clearer rights and responsibilities for manufacturers, importers and distributors,
- stricter requirements for clinical evidence,
- improved traceability,
- more rigorous and regular checks on manufacturers,
- better co-ordination between national surveillance authorities,
- better supervision of the bodies in charge of assessing medical devices,
- A comprehensive, public database on medical devices available on the EU market.

### Next steps

The Commission’s proposals will be discussed in the European Parliament and Council. They are expected to be adopted in 2014 and will start entering into force in 2015.



[http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm)

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## EP NEWS



Barroso at the EP: State of the Union 2012

European Commission President José Manuel Barroso called for «a new thinking for Europe» in his State of the Union address to the European Parliament on 12 September, saying that it was needed to move Europe forward from the continuing financial crisis.

«Securing the stability of the Euro area is our most urgent challenge,» he said. Completing the single market, the economic and monetary union and reaching agreement on a new EU budget for 2014-2020 – due this autumn – are also essential for growth and reform in the EU.

Barroso also underlined a need for greater democracy, saying that the 2014 EP elections should be used to “mobilise all pro-European forces” and to make Europe «ever more democratic».

<http://ec.europa.eu/soteu2012/>

## TOP TIP!

Want help to quit smoking?  
Scan here:



## EU & FC Barcelona team up against smoking



The European Commission and FC Barcelona have joined forces to help Europeans kick their smoking habit. With tobacco accounting for nearly 700 000 premature deaths per year in the EU, both parties want to do their bit to reduce smoking and tobacco-related disease and death.

The «Quit Smoking with Barça» partnership was formalised in September

when FC Barcelona President, Sandro Rosell, visited Brussels to meet Commissioner for Health and Consumer Policy, John Dalli. This partnership brings together high-profile campaigns: the EU Commission's «Ex-Smokers are Unstoppable» and FC Barcelona's «Smoke Free Barça».

More concrete initiatives will follow in 2012/2013.



From left: FC Barcelona President, Sandro Rosell, Commissioner John Dalli & Dr. Jordi Mones

[www.quitsmokingwithbarca.eu](http://www.quitsmokingwithbarca.eu)

## Gold for «Ex-smokers» at advertising awards



Paola Testori-Coggi & Despina Spanou (DG Health & Consumers) with members of Saatchi & Saatchi Brussels

For the first time in history, an EU institution has been awarded the prestigious Euro Effie award for marketing communication.

Two Effies – the Golden and Special Award for best demonstration of innovation in magazine or newspaper advertising – were awarded for the EU's «Ex-smokers are Unstoppable» campaign, launched in 2011 and developed by DG Health and Consu-

mers and Saatchi & Saatchi Brussels.

“It's a great honour for “Ex-Smokers are Unstoppable” to be recognised with such a prestigious award. Currently close to a quarter of a million Europeans are seeking to quit smoking with the support of the campaign», said Paola Testori-Coggi, Director-General for Health and Consumers.

### Top tip! New app for *iCoach*

The highly successful *iCoach*, which has more than 250 000 registered users, is now available as a mobile app both for iOS and Android systems. It offers users easy access to the free health coach even when they are on the move. Find it in the Apple Store under «Exsmokers iCoach» or scan the top tip box.



<http://sp.adforum.com/euro-effie/2012>

## Boosting use of the small claims procedure



European consumers are missing out on the benefits of the EU's Small Claims Procedure because it remains relatively unknown and poorly enforced, despite being a quick, easy and efficient way to resolve cross-border disputes.

The Small Claims procedure has been in place since 1 January 2009. It can be used in cross-border disputes over goods and services where the value concerned is less than €2000.

Health and Consumer Commissioner John Dalli said he was «disappointed to see such a low level of assistance» for consumers who have tried to use the procedure.

According to a recent report by the European Consumer Centres'

Network (ECC-NET), 40% of European consumers who had encountered a problem buying goods or services in the last 12 months had not found a solution. Many national judges are unaware of the procedure and positive rulings are often not enforced in the consumer's home country.

### Next steps

The Commission will:

- Work with court authorities to promote awareness of the procedure;
- Issue a guide for consumers and legal practitioners;
- Make it easier to register a claim by providing forms and information on-line;
- Work with ECCs to promote the procedure amongst consumers and judges.

### Small claims procedure

- Free of charge
- For claims of under €2 000
- Conducted mostly in writing using pre-defined forms

[http://ec.europa.eu/consumers/ecc/docs/small\\_claims\\_210992012\\_en.pdf](http://ec.europa.eu/consumers/ecc/docs/small_claims_210992012_en.pdf)

## Proposal for clearer rules on pollen in honey



Pollen should be considered a natural constituent of honey – not an ingredient – according to a European Commission proposal adopted on 21 September.

It follows a European Court of Jus-

tice preliminary ruling which considered pollen an ingredient of honey, added mainly when the beekeeper collects honey from the hive frame.

The proposal means that EU labelling rules - which require a list of ingredients - would not apply. It does not affect the Court's conclusion that honey containing genetically-modified (GM) pollen can only be placed on the market if it is authorised under the EU's GM legislation.

The proposal must now be discussed by the European Parliament and Council.

<http://curia.europa.eu/jcms/upload/docs/application/pdf/2011-09/cp110079en.pdf>

## IN BRIEF

### John Dalli visits Munich

John Dalli visited Munich in September for meetings with Bavarian Minister of State for Environment and Health, Dr. Marcel Huber. The key points were GMOs, anti-microbial resistance and food labelling.

### World Alzheimer's Day

World Alzheimer's Day took place on 21 September under this year's motto, «Dementia: Living together». Activities focussed on reducing the stigma associated with dementia and helping communities to provide activities and social events for people living with dementia and their carers.

### World Rabies Day

«Combatting rabies in the EU and beyond» was the theme of World Rabies Day on 28 September. The EU currently spends about €30 million annually on oral vaccination programmes in EU countries and border areas & rabies eradication in the Western Balkans.

### Czechs increase traceability for spirit drinks

Czech authorities have introduced new measures to strengthen traceability requirements for spirit drinks produced or bottled in the Czech Republic after 1 January 2012. It follows a decision to ease an emergency ban on the sales or export of alcohol containing over 20% ethanol, imposed on 12 September, after 26 people died from drinking alcohol contaminated with methanol. The Commission will continue to monitor the situation.



## EU adopts list of approved food flavourings

Flavouring substances in food will become even safer and more transparent following the adoption of new rules by the European Commission on 1 October.

They include a list of over 2 100 authorised food flavouring substances as well as another 400 substances that are currently being evaluated by the European Food Safety Authority (EFSA). These may remain on the market until risk assessment and risk management is concluded.

The list will apply from 22 April 2013, after which date all other flavouring substances will be banned. It will be available in a public, on-line database that will allow consumers,

food businesses and national food authorities to easily identify which substances are authorised.

A flavouring substance may only be authorised if it:

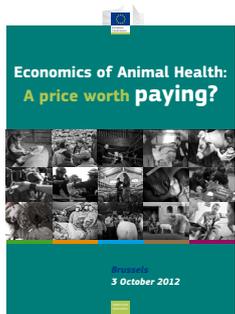
- Poses no risk to consumer health, on the basis of available scientific evidence;
- Does not mislead the consumer.

Commissioner Dalli referred to the decision as a “landmark adoption” that “follows years of efforts to strengthen food safety in the EU.”

Flavouring substances have a long history of safe use in a wide variety of foods including drinks, sweets, cereals, cakes and yoghurts.

[http://ec.europa.eu/food/food/FAEF/flavouring/flavouringsubstance\\_en.htm](http://ec.europa.eu/food/food/FAEF/flavouring/flavouringsubstance_en.htm)

## Vet week focus on animal health economics



The EU's annual vet week conference brought together vets, policy makers and senior experts from across the world under this year's theme: «Economics of animal health: a price worth paying?»

The conference, which took place

in Brussels on 3 October, focussed on the importance of animal health and its role in the economy.

In his closing remarks, EU Commissioner Dalli spoke of a need to combine food security and sustainable development, saying that «animal health lies at the heart of this key challenge.» He added that the Commission plans to adopt a package of proposals to reinforce the safety of the food chain in coming months.

[http://ec.europa.eu/dgs/health\\_consumer/information\\_sources/ahw\\_events\\_en.htm](http://ec.europa.eu/dgs/health_consumer/information_sources/ahw_events_en.htm)

## COMING UP

**16-17 October:** EU conference on **childhood immunisation**, with a focus on strengthening and monitoring immunisation programmes and promoting vaccination (Luxembourg).

**24 October:** International Conference on the implementation of EU animal slaughter rules (Brussels).

**5 November:** This year's **EU Food Information Day** will take place under the theme «healthier choices for a healthier life» with a special focus on health claims and nutrition labelling (Brussels).

**12 November:** Conference to mark 10 years of the European Food Safety Authority, «Taking stock and looking forward» (Parma, Italy)

**14-15 November:** Joint meeting of the EU Platform for Action on Diet, Physical Activity and Health and High Level Group for Nutrition and Physical Activity (Brussels).

**28 November:** The BBC's **Good Food Show** begins in Birmingham, UK, with the participation of DG Health and Consumers.



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