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NOTE

from:	General Secretariat
to:	Delegations
Subject:	Partial summary record of the meeting of the **Committee on the Environment, Public Health and Food Safety (ENVI)** of the European Parliament, held in Brussels on 26 September 2013 (item 18)

The meeting was chaired by Mr GROOTE (S&D, DE).

Item 18 on the agenda
Exchange of views with Neven Mimica, Member of the European Commission responsible for consumer policy
ENVI/7/13658

The exchange of views with the Commissioner responsible for consumer policy Mr Neven MIMICA took place as part of the structured dialogue between the EP and the Commission.

The Commissioner delivered the speech set out in the annex, in which he addressed the priorities of the Committee on the Environment, Public Health and Food Safety until the end of the legislature as well as topical issues such as the Cosmetics Regulation and draft regulations on medical devices and *in-vitro* medical devices, on which the ENVI committee had adopted reports the previous day.

Mr MIMICA also presented his main priorities for the rest of the Commission's mandate, notably to consolidate the legislative framework and to support the adoption of the pending legislation (on medical devices and in-vitro diagnostics, product safety and bank accounts); to ensure better enforcement of the existing legislation on consumers' rights (online hotel bookings, hidden charges in on-line games, online air travel); and to create tangible benefits for consumers and to empower them to look for better deals in areas such as energy or telecommunications.

The ensuing discussion was broadly dedicated to the issue of medical devices and *in-vitro* medical devices, with interventions of the rapporteurs Ms ROTH-BEHRENDT (S&D, DE) and Mr LIESE (EPP, DE). They recalled that the ENVI committee's aim was to ensure that Member States would guarantee coherent application of European safety rules, to help bolster the certification authorities and to centralise authorisation procedures for certain devices, especially following the recent scandals on defective breast implants and prosthetic hip replacements. Ms ROTH-BEHRENDT regretted that the committee had not retained her proposal for preliminary marketing authorisation and considered that the proposal should not be watered down any further during the negotiations with the Council. She stressed that she had been subjected to very aggressive lobbying and called on Mr MIMICA to accept the amendments suggested by ENVI and the Commission to clearly support the EP position. Mr LIESE (EPP, DE) also expressed his satisfaction with the reports adopted and called on the Commission to encourage the Council to examine the proposal on the *in-vitro* medical devices as soon as possible, as the rules directly affect the health of European citizens and consequently European institutions should work swiftly to move the legislation forward. Several speakers stressed the importance of drawing up clear and binding rules on medical devices and *in-vitro* medical devices but without disadvantaging enterprises which respect the legislation (Ms AUCONIE (EPP, FR), Mr DAVIES (ALDE, UK)).

Some other issues were also raised by speakers: challenges concerning the application of rules on animal testing by the cosmetics industry (Mr DAVIES (ALDE, UK)), fire safety in hotels (Ms McAVON (S&D, UK)), services of electricity providers in Members States and prices of electricity for consumers (Ms LYUBCHEVA (S&D, BG)). Croatian members of the committee, Ms BORZAN (S&D) and Ms ŠUICA (EPP), raised the issue of the necessity to ensure that the same product quality is available to customers in all Member States.

In his statement in reply, Mr MIMICA stressed that the Commission appreciated the efforts made in the ENVI committee on medical devices and *in-vitro* medical devices but that he would not be able to express its position on amendments voted for on the previous day until the amendments had been analysed. Concerning the Cosmetics Regulation and animal testing, he stressed that the Commission was determined to implement rules as fully as possible. Mr MIMICA also reiterated the Commission's readiness to act on other issues raised, for the benefits of European customers.

ANNEX

COMMISSIONER MIMICA

STRUCTURED DIALOGUE WITH ENVI COMMITTEE

EUROPEAN PARLIAMENT, BRUSSELS

26 SEPTEMBER 2013

SPEECH

Chairman, Honourable Members of the Committee,

It is both an honour and a pleasure to be here with you today. I very much welcome this opportunity to discuss a number of initiatives on which we are working together.

As this is my first structured dialogue since my hearing, I would, at the outset like to present my main priorities for the rest of this Commission's mandate.

My first priority is to consolidate the legislative framework and to support the adoption of the pending legislation on medical devices and in-vitro diagnostics, product safety and bank accounts during this legislature.

My second priority is to ensure better enforcement of the existing legislation. Rights which are not enforced do not exist. My ambition is to explore a number of areas in which the Commission could assist national authorities to achieve more effective enforcement. This will include:

- first, user reviews in online hotel bookings; consumers rely on those reviews although we know that some can be misleading and fraudulent;

- second, hidden charges in on-line games/in-app purchases, in particular targeting kids; past enforcement actions showed significant unfair commercial practices;

- and consumer rights in online air travel, as the relevant consumer rights are particularly often violated.

Thirdly, my aim is to create tangible benefits for consumers and to empower them to look for better deals in areas such as energy or telecom. Consumers can save money by using their rights to change contracts or even providers, but experience shows that they need to be encouraged, in particular through reliable information.

Today, however, I want to focus on the issues which are most pertinent for this Committee.

I will start with a vitally important file – the on-going revision of the **medical devices** legislation.

I am glad that, yesterday, your Committee voted on its reports concerning the two Commission proposals.

Let us not forget – these proposals are essential for strengthening patient safety and confidence.

Many amendments were proposed by your Committee on both texts, and I would like to sincerely thank those of you who have been working so intensively and constructively on these two reports.

I am fully aware of the complexity of this work and I am especially grateful for the dedication of Ms Roth-Behrendt and Mr Liese – the two Rapporteurs – as well as the Shadow Rapporteurs.

You will understand that I cannot, at this moment, give you the Commission's position on the amendments which we first need to analyse thoroughly. My overall impression is that generally your amendments do go in the right direction. However, there is clearly a need to carefully look into important issues.

It is of the utmost importance – for the Commission, but above all for patients, healthcare professionals and industry – that these two proposals are adopted under this legislature. Yesterday, this Committee sent a very clear and important political signal in this respect.

Your desire to make progress is shared by both the current Lithuanian Presidency and the future Greek Presidency. My services and I are in close and regular contact with both. We have coordinated closely with the Lithuanian Minister who shares our goal to see this file adopted within this mandate.

I believe the political will and commitment is clearly there on all sides. The Commission will continue to provide full support in order to meet our common objective of securing legislation which can ensure the highest levels of patient safety.

It is important that the final outcome considerably strengthens the rules for the placing on the market of medical devices, in particular with regard to:

- the assessment of high risk devices;
- the requirements on notified bodies; and
- improved vigilance and market surveillance.

At the same time, the rules must remain proportionate to ensure that Europe stays at the forefront of innovation in this important sector.

The entry into force of the new legislation will, however, inevitably take some time. This is why the plan of immediate action, agreed between the Commission and the Member States, is of such critical importance.

The plan focuses on four main areas: the functioning of notified bodies; market surveillance; vigilance and follow-up of serious incidents; and transparency.

Good progress has been made on many of the points of the plan. For example, two days ago, the Commission adopted a Commission regulation to ensure consistent application by Member States of the minimum criteria set out in the current legislation to be met by the notified bodies and a recommendation clarifying what is expected by notified bodies when they assess manufacturers.

In the next weeks we will present a Staff working document detailing the progress made and the further steps that we propose.

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Turning to **cosmetics**, 2013 marked the entry into force of the new Regulation and of the full ban on animal testing. These were important milestones.

The Cosmetics Regulation increases safety through clear requirements for the safety assessment of finished products, strengthened market surveillance and better information on products. New tools such as the Cosmetic Products Notification Portal help the competent authorities and anti-poison centres to better fulfil their tasks.

The Commission has invested immense efforts in implementing the Cosmetics Regulation. However, this is only the beginning – more challenges lie ahead.

The regulation of fragrance allergens is certainly one of them. We must ensure sufficient and appropriate consumer information for consumers suffering from allergies. Restrictions on the use of substances are also needed, but must be proportionate and scientifically well-founded. A ban should be limited to the strongest allergens.

Challenges remain also in the field of alternatives to animal testing. The Commission's decision to maintain the marketing ban gave an important signal, in Europe and beyond, in favour of animal welfare and innovative approaches to safety assessment.

But we cannot ignore the fact that we do not yet have the tools available for a full safety assessment based on alternative methods. I will thus strongly support research and international cooperation in this field and I am sure that I can count on your backing.

Chairman, Honourable Members,

Thank you for your attention – and thank you once again for the opportunity to address this Committee.

I now look forward to hearing your views and answering your questions.