EP PLENARY

MEDICAL DEVICES + IN VITRO DIAGNOSTIC MEDICAL DEVICES

21-23 OCTOBER 2013

OPENING SPEAKING NOTE

President, Honourable Members,

The two proposals on medical devices and *in vitro* diagnostics that we are debating today are of the highest importance for patient safety.

Current legislation has shown shortcomings far beyond the PIP breast implant scandal. This was a case of fraud which even through the toughest pre-market control would not have been prevented.

But we need better clarity for innovative and borderline products. We need stricter requirements for notified bodies and for their oversight of manufacturers. Without changing the law, unannounced audits will not become obligatory. With such unannounced audits even the PIP scandal, though being the case of fraud, would have been detected much earlier.

These are just a few examples, why the revision is needed. And why it is needed urgently to fully restore the trust of patients, consumers and healthcare professionals in the regulatory system.

For this reason, let me thank the rapporteurs – Ms Roth-Behrendt and Mr Liese – together with the shadow rapporteurs for their determination, expertise, and personal commitment towards advancing these two important files.

I will not explain to you the details of the Commission's proposals again, as you are well familiar with them.

Instead, let me address two key elements which have been subject of particularly intensive discussions over the last couple of months, including in the Parliament.

As regards the system for approval of devices, the Commission's proposal was to maintain a system of self-certification by the manufacturer in case of low risk and of verification by notified bodies in case of medium-risk.

In case of high risk, the Commission has proposed to allow public authorities to have a second look at the assessment by the notified body in specific cases, e.g. where the product is particularly innovative or where particular problems occurred

with the category of products. This was meant as exceptional safeguard. In fact, our impact assessment had assumed something like 50 products to be scrutinized per year.

In your committees, different changes have been proposed. I have no problem to accept that the Commission proposal can be improved. It may not have considered sufficiently for example how to ensure the necessary technical and scientific expertise for the scrutiny. But overall I believe that the scrutiny procedure as form of exceptional safeguard is the best compromise to ensure a high level of patient safety while avoiding too burdensome processes.

For the reprocessing of single-use medical devices, I strongly believe that we need European rules that fill the current regulatory gap. The Commission has proposed strict rules on reprocessing based on the latest scientific evidence. It would allow the practice of reprocessing to develop further under clear and safe conditions leading to potential savings for healthcare systems.

I have followed attentively the different ideas that have been put forward in the Parliament on the reprocessing. And I am open of course to carefully analyse the amendments you will be voting on after this debate in order to see whether they would further improve the patient protection.

Apart from these issues, there are many other suggestions from the Parliament which I am happy to consider favourably. You propose for example to strengthen the provisions on ethics committees or on minors and incapacitated patients. I am open to these changes as long as they remain in line with the provisions that are currently negotiated in the context of the proposed Regulation on clinical trials on pharmaceuticals.

Similarly, there are a number of specific issues on the proposal concerning ***in vitro*** **diagnostics**, which in my view also are valid and acceptable in principle. This concerns for example the in house exemption and the counselling and informed consent in the field of genetic tests.

President, Honourable Members,

Now I am very interested to hear your views on these as well as on other issues on which you think the Commission proposals needed to be improved.

I cannot give you a final position on all details. But I commit to carefully analyse all the amendments you will adopt on both of these proposals. My guiding principles will be the aim of ensuring the highest level of patient and consumer safety whilst making sure that innovation continues to flourish.

I count on you, Honourable Members, to give a strong mandate to the rapporteurs – Mrs Roth-Behrendt and Mr Liese, which will pave the way for successful negotiations, so that together we can deliver for citizens by concluding these important files within the current Parliamentary term.

Thank you.