Speech of Rolf Schwanitz

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Key issues of the German EU Presidency in the field of Pharmaceuticals

PPRI Conference

Pharmaceutical Pricing and Reimbursement Information

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The German version – as presented – is binding

Ladies and Gentlemen,

it is a great pleasure to speak to you here on behalf of the German presidency on the last but one day of the German presidency. Generally speaking, one can easily say that European politics is in a flux. This certainly also applies to European health politics. European health politics is undergoing a tremendous change. While health may be seen as historically neglected by European politics, it is rapidly gaining importance in EU politics due to the demographic change, that all member states are equally confronted with. Furthermore, the health sector becomes more important in EU-politics due to its great social and economic potential.

Just to recall: The Lisbon objective is to build Europe the most competitive, innovative and knowledge based economy. Hereby, the Lisbon agenda focuses primarily on employment, innovation and research.

All across Europe, the health sector is one of the few sectors with a vast growth potential. European policy makers must politically substantiate this social and economic key role of the health sector. Here, we see innovations in the pharmaceutical field in the front line.

The pharmaceutical and biotech industry in Europe with over 600.000 employees, about 160 Billion Euro annual turnover and about 25 Billion Euro annual investment in R&D can be seen as a main pillar of this huge economic potential.

This is why we picked "Innovation" as a key theme for the German presidency in the health sector. A prerequisite for all innovation is a favourable regulatory framework. The German presidency believes, that it is an original duty of politics to provide a proportionate regulatory environment for innovation. Therefore, the German presidency pushed forward the draft regulation on advanced therapy as well as the reform of the medical devices directives.

Our aim was to construct both pieces of legislation in such a way as to safeguard both, the innovativeness and competitiveness of the European market for drugs and medical devices and the high safety and quality standards for patients.

With our conference in Bonn in the beginning of June we focussed on a rather visionary topic with regards to the pharmaceutical sector: "pharmaceutical innovation: possibilities and limits of personalised medicines".

Our aim is to strengthen the innovativeness of the European pharmaceutical industry and to safeguard Europe as the central business location for the pharmaceutical industry. We expect very important innovations in the area of personalised medicines in the near future.

From our point of view, personalised medicine has the potential for a change of paradigm in the pharmaceutical sector, away from the traditional principle of "one fits all". This new approach aims for a patient-specific-application of drugs. Personalised medicines may bring up new and better therapies for the patients as it takes the specific needs of population groups into greater account. Furthermore, it may enhance the efficacy of medications and avoid undesired effects more reliably.

This could have obvious benefits for the limited resources of health care systems as otherwise, wrong medication and undesired effects would be cost intensive.

My Minister Ulla Schmidt presented the results from our conference to the ministerial meeting of the Pharmaceutical Forum on Tuesday. The German presidency fully supports the work of the forum. We believe that this linkage offers great potential for the future of healthcare in Europe.

The work of the Pharmaceutical Forum has shown that – generally speaking – all Member States are willing to support innovative medicines in favour of Europe's patients.

However, Member States have to ensure that these innovations are practically accessible. Access includes – and this is the crucial point – the affordability of innovative medicines!

Against this background, my minister Ulla Schmidt raised three questions at the Pharmaceutical Forum:

Firstly: Can we afford that every Member State uses a different definition of the term innovation?

Secondly: Can we afford that every Member State tries to find individual solutions for ensuring its patients' access to innovations?

Thirdly: Can we afford that even information on prices for innovative medicines is not being exchanged between the Member States?

The German presidency sent out a clear message by answering: No, we cannot afford this!

To some this might sound visionary but we truly believe that – in the long run – we will only be able to ensure equitable access to innovations for all patients if we set clear framework conditions for pricing and reimbursement at a European level.

Thank you very much for your attention.