1. Is the New approach, as it is now, and the European legislation in MD field ready for dealing with new technologies and products?

In 2003 the European Commission came in their report to the European Parliament and to the European Council to the conclusion that the Medical Devices Regulation based on the principles of the New Approach is an appropriate regulation. At that time the Commission and the Member States considered a limited need of improvement and amendment of the Directives 90/385/EC and 93/42/EC. These amendments were negotiated and introduced in 2004-2007. These changes are in place since the 21st of March 2010. The important improvements in the fields of clinical evaluation and clinical investigation and the introduction of an representative design evaluation for mid-risk devices (class IIa and class IIb) could be considered as step to make the regulation ready for the next future.
It is one of major benefits of principle a new approach regulation that it is based on a high level of flexibility which enables the regulation to deal with new technologies etc.
A high level of flexibility in the regulation also requires flexible and fast actions and decisions making by the involved parties (manufacturers, Notified Bodies, standard bodies, competent authorities, European Commission).
Analysing the current practice it can be concluded that in particular the processes in the standardisation are to slow and the European decision making procedures don't work in an appropriate way.
In these fields we see the need of further development of the regulation. New procedures or even new structures for making European harmonised decisions seem to be necessary. Also in the field of designation and monitoring of Notified Bodies improvements will be necessary. There is a need of a harmonised high level of performance of Notified Bodies. The designation process must be based on same requirements in every Member State and in countries where Europe signed Mutual Recognition Agreements. Expertise of designating authorities from other Members states should be involved in the designation process. The designating authorities should establish a peer review system by which they can reach a uniform high level of Notified Bodies performance by designation and regular monitoring of them.
With these changes the European Medical Devices regulation could stay in the framework of the New Approach also in the future. The tendency in other "New Approach" sectors to move the responsibility for the monitoring (and to a certain extend the designation) of Notified Bodies and for requirements on Notified Bodies to the European Co-operation for Accreditation which is a private Company under Dutch law is in this context a critical process.

2. Is it necessary to modify the legislation only for health protection reasons or it is possible to provide for changes due to global harmonization and trading concerns?

There is only a limited need to modify or polish the European Medical devices regulation due to global harmonisation aspects. The Global Harmonisation Task Force has established a global model for Medical Devices regulation which is very close to the European regulation.

3. What are your expectations about European Database Eudamed? Will it be useful for market surveillance, vigilance, clinical investigation management and/or other issues?

Due to serious concerns of the European Parliament with regard to the usefulness and functioning of EUDAMED the European Commission got the task to provide in 2012 a report on the functioning of EUDAMED. Based on this report further consequences have to be discussed. In the history several mistakes have been implemented. In particular the intention that EUDAMED should sample as much as possible all information on devices and manufacturers leads to a database which is not at least on the basis of the German experiences useful for e.g. market surveillance or vigilance purposes.
In the context of the introduction of an global Unique Device Identification system for Medical Devices a so-call European UDI database have to be established. EUDAMED could be re-designed in that way. The currently envisaged content (already under discussion) of the UDI Database would be sufficient to perform an adequate market surveillance and vigilance.

4. What purposes you have with the aim to solve the increasing area of borderline products (MP/MD, cosmetics/MD, biocides/MD…)

At the end all products have to be safe when entering the market regardless under which regulatory umbrella they are regulated. In this context it is of main interest to clarify under which regulation specific products should come to the market. By assessing the safety of such products the essential requirements of the other regulatory frameworks have to be fulfilled.

An inter-sectorial committee within the Commission and with the participation of Member States experts which provides fast decisions on theses issues could be established.

5. What about the proposal of a central evaluation for some high risk devices?

A central evaluation of some high risk products is a break with the principle of the New Approach. Existing experiences with such centralised evaluations in other regions of the world don't provide a higher level of safety, but higher costs and a serious delay of patient access to medical innovations. A centralised evaluation could be in the future necessary when Notified Bodies fail or are not able to maintain the necessary experiences and resources to assess in particular new "critical" technologies.

6. What measures you consider should be adopted against counterfeiting?

With regard to counterfeiting an intensified effective market surveillance should be the first step to improve the situation. Market surveillance authorities should intensify the co-operation with the customs authorities. The coming UDI requirements will make it more difficult to counterfeit medical devices and to feed the counterfeited products into the regular distribution chain.

7. What is your opinion about MD reprocessing?

Reprocessing and refurbishing of medical devices are a critical processes which require highest carefulness and technical competence. In Germany a regulation is in place which sets out technical and organisational requirements for institution providing reprocessing or refurbishing services. This regulation is under permanent evaluation with regard to their appropriateness and the need for amendments, improvements etc.

The German regulation doesn't distinguish between the reprocessing of a single use device or a multi-use device. Instead of that a classification tableau was established by which the devices are classified with regard to their risk related to (or with the difficulties to reach) a proper reprocessing.
With increasing risks the requirements are increasing. All re-processors have to validate their processes and the functionality of the reprocessed devices. Reprocessing critical devices requires the involvement of a third party which certifies the processes and the quality management system of the re-processor.