Patient-MedTech Dialogue

MDR/IVDR Workshop

1 June 2017, Thon Hotel EU, Brussels

Report

1. Introduction

On the 1st of June 2017 a workshop on two new EU regulations for medical devices and in-vitro diagnostics (MDR/IVDR) was held in Brussels in the realm of the Patient-MedTech Dialogue platform.

The aim of the workshop was two-fold: (i) for patients to acquire knowledge about the new Regulations and to have the opportunity to ask questions, and (ii) for the medtech industry to understand patients' perspectives on potential benefits/concerns about the new Regulations. There were about 30 representatives at the meeting from national and European patient organisations and medtech companies. Two representatives from DG GROW were also present throughout the day to provide their perspectives on the topics discussed.

2. Discussions of the day

2.1 Overview of changes from the previous legislations

John Brennan (Director, Regulatory Affairs and Industrial Policy, MedTech Europe) kicked off the Workshop by presenting an overview of the key changes in the new regulations. He explained that there will be major changes that need significant investment of resources from all players, such as Competent Authorities of Member States, Notified Bodies and industry to comply with all new requirements in time. Industry is committed to timely implementation of requirements with little or no disruption for its customers. The implications will even more significant for the IVD industry, where almost all test kits will new face an external assessment through Notified Bodies.

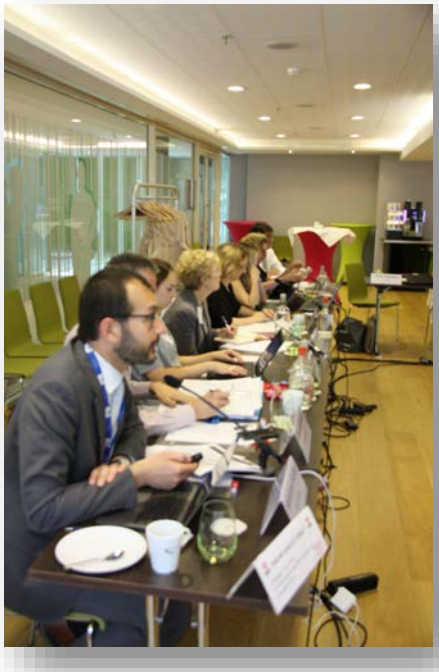
Some of the major changes from the previous legislation for the IVD industry include:

- Completely revamped risk-based classification scheme; where most of the test kits will now need oversight from the Notified Bodies. Early advice in this matter will be important, especially to address potential grey areas in classification.

- Performance evaluations of the technology to ensure that the tests are sufficiently precise, are targeted to the appropriate population and prove the relation between the result of the test and the related disease.
- Conformity assessment by Notified Bodies to ensure that the concerned IVD products comply with all legislative requirements before they can be placed on the market and made available.
- Transparency: a central database called EUDAMED will be available to citizens, showcasing available products and information on vigilance.

<u>Some key changes for the Medical Device industry:</u>

- A new scrutiny process for high risk innovative products requiring a Notified Body to consult with an expert panel on the product's clinical file, before placing such product on the market.
- Device identification and labelling to help traceability
- Similar transparency measures through the EUDAMED database, where questions still need to be addressed as to what type and level of information is of value for the public and for professionals. It is about delivering highest valuable level of transparency, but protecting confidential business information and avoiding 'data dump'.



John reiterated that the work is just beginning as there are still 80 delegated and implementing acts and many uncertainties to clarify for the implementation of the Regulations.
European Commission representatives Salvatore Scalzo and Vincent Houdry also presented a few points on the new Regulations, including the process within the Commission to coordinate the work on the implementation. Due to the large number of secondary legislative acts, the Commission decided to prioritise the following (non-exhaustive):

- Notified Bodies
- Governance
- Common specifications of devices without a medical purpose
- Establish EUDAMED and UDI (Unique Device Identification) systems providing access to useful and relevant information regarding the device
- Mandate SCHER (Scientific Committee on Health and Environmental Risks) to produce guidelines on phthalates

The Commission also identified two major points for patients that are relevant in the new Regulations (i) implant card to be given to patients with implanted devices and (ii) financial mechanisms for patients in case of a defective technology.

The session was followed by a discussion with questions around the structure of a new Medical Device Coordination Group (MDCG) composed by Member State experts and chaired by the Commission that will be set up to carry out further work on the implementation. It was clarified that the expert group will include about 20 people and will be set up as soon as possible. It will also be possible for patient associations to apply to this group, if applicable for the subject at hand.

2.2 Focused discussions

The Patient-Medtech Dialogue Steering Committee identified three key areas to discuss in more depth, as outlined below. At each point, the participants heard from both patient and industry representatives and had the opportunity to ask their questions.

2.3 Clinical evaluation and clinical performance

Mary Lynne van Poelgeest-Pomfret (President of World Federation of Incontinent Patients) talked about the value of proactive and meaningful patient involvement. Mary Lynne reflected on what patients need in order to be able to undertake clinical evaluations:

- Knowledge of the disease
- Basic understanding of the measures used
- Motivation
- How and where should evaluations be undertaken?
- How should the results be recorded and played back?

Following her presentation, Carine Cochereau (Regulatory and Clinical Director EMEA at Cardinal Health) and Celine Bourguignon (Director Global Regulatory Policy at J&J) talked about clinical evaluations of medical devices and in-vitro diagnostics (IVDs) respectively. There is a key difference in the evaluation of these technologies, due to the fact that IVDs do not touch the human body, they merely provide information. Therefore, for medical devices information is required on their safety and performance, while for diagnostics their accuracy and relevance need to be demonstrated.

2.4 Transparency measures and information to patients

Isabel Saraiva (Vice President of RESPIRA) mentioned that the main challenge in this respect is to transform information into knowledge. She highlighted that working together with the medical technology industry and improving the information flow between industry and patients are crucial elements moving forward in this field.

Oliver Bisazza (Director Regulatory Policy EMEA at Medtronic) reiterated that industry supports increased transparency, however we need to be cautious for two key reasons (i) personal data protection and (ii) commercially confidential information. The latter is particularly important for the medtech sector, as we do not benefit from the same type of IP protection as pharma. There are still many questions as to how to evaluate whether the information provided is meaningful and how to best make the information available to all.

2.5 Stakeholder involvement

Katie Gallagher (Policy Adviser at EPF) talked about the need to involve patient organisations in the implementation of the MDR and IVDR. In fact, patients have a unique expertise as users of medical technologies. However, there is no provision in the new Regulations to involve patients' organisations. Katie also suggested a few ways in which patient organisations can get involved through a variety of actions.

John Brennan (Director Regulations and Industrial Policy at MedTech Europe) agreed that it is unfortunate that stakeholders are only consulted at the end of the process according to the current path. He addressed to the Commission to revisit the foreseen stakeholder policy and to involve all stakeholders from the beginning of any further legislative or guidance work. This would surely contribute to the quality and feasibility of secondary acts.

3. Conclusions & next steps

Nicola Bedlington (Secretary General, European Patients' Forum) and Tanja Valentin (Director, Government Affairs & Public Policy at MedTech Europe) thanked everyone for their participation. The European Commission highlighted that they are very much open for stakeholder input and that patient organisations are welcome to contact them.

A tour de table of feedback on the Workshop showed that the participants felt that they learnt a lot, they would appreciate further collaboration in the future; e.g. having such workshops replicated to individual patient organisations' needs. Having DG GROW be represented and contributing to the workshop was in particular highly valued by all participants.

As a next step, the Steering Committee will discuss the conclusions and learnings from this workshop and how to best move forward. In addition, a continued discussion in the realm of the Patient-MedTech Dialogue will continue on other relevant topics.

Furthermore, in December 2017, a joint patient platform meeting with other healthcare industry associations, including MedTech Europe will be organised to discuss cross-cutting topics of interest.

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