Patient-MedTech Dialogue Workshop on the new Medical Device and *In-vitro* diagnostics Regulations

DRAFT

1st June 2017 13.30-18.00 hrs CET
Brussels, Thon Hotel EU

Objectives

The objectives of the workshop are two-fold: for patients to acquire knowledge about the new legislation and to have the opportunity to ask questions, and for medtech industry to understand patients' perspectives and potential benefits and concerns about the new legislations (MDR/IVDR).

Participants:

The workshop is aimed at national and European patient organisations, both EPF and non-EPF members, and medtech companies.

Venue:

Thon Hotel EU, Rue de la Loi 75, 1040 Bruxelles

AGENDA

12.30-13.30 ***Networking lunch*** *(optional)*

- 13.30 – 13.40 **Welcome & Introduction** *(Nicola Bedlington, EPF & Tanja Valentin, MedTech Europe)*
- 13.40 – 14.00 **Patient-MedTech Dialogue: 2017 outlook** *(Nicola & Tanja)*
- 14.00 – 15.00 **Overview of changes from previous legislation** (*John Brennan, MedTech Europe and an industry speaker)*

15.00-15.15 Coffee break

- 15.15 - 17.45 **Focus areas** *(each session will have a patient and an industry speaker)*
  - 15.15 – 16.05 **Clinical evaluation and clinical performance**
    Discussion about clinical requirements regarding the safety and effectiveness of a device and an IVD.
  - 16.05 – 16.55 **Transparency measures and information to patients**
    Discussion about measures that aim at improving quality and availability of information on medical devices and IVDs for patients and the public.
  - 16.55 – 17.45 **Stakeholder involvement**
    Exchange of views on the relevance of timely involvement of stakeholders in the decision making process and identification of potential actions.
- 17.45 – 18.00 **Conclusions & next steps** *(Nicola & Tanja)*