EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 7/11/2017

NOTE TO THE FILE

Subject: **Meeting with Serge Bernasconi, CEO, MedTech Europe on 26 October 2017 – [redacted] and Health Technology Assessment**

Participants:

Guests: *MedTech Europe: Serge Bernasconi (CEO);* [redacted]

Commission: *A. Peltomäki (DDG),* [redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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- MTE explained its disagreement with the project of new Regulation on health technology assessment (HTA) under preparation by DG SANTE. Industry fears that it might block innovation as it is supposedly the case in France where HTA is commonly applied to medical devices and where innovation would reach the market 3 or 4 years later than in the rest of Europe. According to MTE, procurement is the main way to buy devices in MS, which would be the reason why HTA at national level would be inadequate. MTE is in favour of coordination in that matter but against any legislation (which would create additional burden to the EU industry, already under strong pressure for the implementation of the medical devices and IVD regulations), and supports qualitative procurement.
- The Commission underlined that the proposal in preparation in DG SANTE was the result of a long reflexion process (public consultation and impact assessment), based on the principles of better regulation. The inter service consultation should be launched rather soon.

Next steps

Another meeting on HTA is foreseen with MedTech Europe and the Cabinet of Commissioner Bieńkowska on 8 November.