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

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 13/11/2017

NOTE TO THE FILE

Subject: **Meeting with Serge Bernasconi, CEO, MedTech Europe on 8 November 2017 - Medical devices: [redacted] and health technology assessment**

Participants:

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

Commission: *CAB: Agnieszka Drzewoska, Carsten Bermig*
DG GROW: [redacted]

- [redacted]

[redacted]

[redacted]

- MedTech Europe explained its disagreement with the project of new Regulation on health technology assessment (HTA) under preparation by DG SANTE. According to the industry, HTA for medical devices is not useful for price and reimbursement decisions in the MS, except for France. MedTech Europe gave the example of a medical device that had to go through several evaluations requested by MS but without any guaranty of outcome.
- MedTech Europe insisted on the fact that the added value of medical devices is also dependant on the skill of the surgeon who uses the device, so the added value can only be assessed after the device is put on the market, when real life data is available.
- According to MedTech Europe, procurement is the main way to buy devices in MS, which would be the reason why HTA at national level would be inadequate. MedTech Europe is in favour of voluntary coordination in that matter but against any

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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 Cabinet underlined that the proposal is still in the preparation phase in DG SANTE.

Next steps

MedTech Europe will provide the Cabinet of Commissioner Bieńkowska with good example of quality procurement in the health sector.

Contact: [redacted]

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