



EUROPEAN COMMISSION

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

Consumer, Environmental and Health Technologies

Health Technology and Cosmetics

Brussels, 21.03.2018

GROW/D4 [REDACTED]

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NOTE TO THE FILE

**Subject: Meeting between Antti Peltomäki and MedTech Europe
Brussels, 14 March 2018**

Participants: A. Peltomäki (DDG1), [REDACTED]

[REDACTED]

Visitors: S. Bernasconi (CEO) [REDACTED]

[REDACTED]

Mr Bernasconi, CEO of MedTech Europe, requested an appointment to follow-up on a previous meeting held on 26 October 2017. The following issues were discussed: [REDACTED]

[REDACTED] the proposed EU legislation on EU collaboration in the area of Health Technology Assessments (HTA); [REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. NEW REGULATION ON HTA

- MedTech indicated that they generally support cooperation among Member States in this field. However, they mentioned that they receive conflicting messages from involved parties as to the objective of the current Commission's proposal. The EUnetHTA Joint Action Programme was reported by MedTech as having mentioned the possibility of establishing future synergies between HTA evaluators and medical device expert panels or HTA work looking at safety aspects. This is a matter of serious concern for them.
- DG GROW indicated that it stands clearly from the Commission's proposal the idea that the HTA process shall not interfere with the CE marking of the medical devices which is performed before the health technology assessment.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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■ [REDACTED]
[REDACTED]
[REDACTED]

■ [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Note takers:

[REDACTED]