

[REDACTED]

From: [REDACTED]
Sent: mercredi 13 décembre 2017 16:32
To: GROW D4
Subject: FW: HTA Cooperation: MedTech Europe Input- -Ares(2017)6078388

From: [REDACTED]
Sent: Wednesday, December 13, 2017 4:11 PM
To: [REDACTED]
Cc: [REDACTED]; 'Serge Bernasconi'; [REDACTED]
Subject: RE: HTA Cooperation: MedTech Europe Input

Dear [REDACTED]

I would like to thank you for sharing with us the "Briefing note on HTA cooperation and EU legislative initiative".

We have read your paper with attention and forwarded it to DG SANTE for information. As we already had several meetings on HTA for medical devices with MedTech Europe in the last weeks, I think there is no need for an additional meeting on the same topic at this stage.

Let me just provide you with some written comments on your briefing note:

As you refer in your briefing note to the HTA network strategy from 2014, I would like to underline that the HTA Network is a voluntary network gathering all Member States, Norway and Iceland. It has been created by Directive 2011/24 on the application of patients' rights in cross-border healthcare. As is the joint action EUnetHTA; the HTA network is driven by Member States, not the Commission. Therefore, it represents the view of the Member States not the view of the Commission.

Regarding the interference you fear between the certification process of medical devices and HTA, please note that the definition of HTA clearly express that "it is a measure of the added value of a new technology in comparison to existing technologies/current standard of care". HTA is therefore complementary to the conformity assessment procedures foreseen in the legislation on medical devices; the added value can only be measured after the products has been assessed according to the legislation, avoiding any interference between the two processes. "Health technology assessment (HTA) measures the added value of a new health technology in comparison to existing technologies/current standard of care. HTA is defined as a multidisciplinary process that summarises information in a systematic, unbiased and robust manner about the medical, economic, organisational, social and ethical issues related to the use of a health technology. The goal of HTA is to support decision makers at national, regional or local level in their efforts to ensure that patients are treated with the best available treatment while keeping the health budgets under control/in balance."

https://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_it)

Hope this is useful.

Kindest regards

[REDACTED]

[REDACTED]



European Commission

DG for Internal Market, Industry, Entrepreneurship and SMEs
Health Technology and Cosmetics
Unit GROW D.4

Avenue d'Auderghem 45 [REDACTED]

From: [REDACTED]
Sent: Tuesday, December 12, 2017 11:13 AM
To: [REDACTED]
Cc: [REDACTED]; Serge Bernasconi; [REDACTED]
Subject: RE: HTA Cooperation: MedTech Europe Input

Dear [REDACTED]
Yes of course – here you go.
Warm regards,
[REDACTED]

From: [REDACTED]
Sent: Tuesday, December 12, 2017 9:59 AM
To: [REDACTED] a
Cc: [REDACTED]
Subject: RE: HTA Cooperation: MedTech Europe Input

Dear [REDACTED]
We do not manage to open your attachment. Could you please send it back ?
Many thanks
[REDACTED]

From: [REDACTED]
Sent: Tuesday, December 12, 2017 5:47 AM
To: [REDACTED]
Cc: Serge Bernasconi; [REDACTED]
Subject: HTA Cooperation: MedTech Europe Input

Dear [REDACTED]

I am pleased you send you and [REDACTED] the attached MedTech Europe input regarding HTA, and specifically regarding the forthcoming proposal for EU legislation on HTA Cooperation.

We would value the opportunity to meet with you, to discuss these points in person - is that possible before the Christmas break?

Thank you and warm regards,
[REDACTED]

[REDACTED]
[REDACTED]

