

Ad Hoc Synergy Group between Regulators and HTA

8th STAMP Meeting

8-12-2017



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Ad Hoc Synergy Initiative

- * HTA Network
- * HTA Reflection Paper



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels, 10 November 2016

**HTA NETWORK REFLECTION PAPER ON
“SYNERGIES BETWEEN REGULATORY AND HTA
ISSUES ON PHARMACEUTICALS”**

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

Ad Hoc Synergy Composition

- * **Ad Hoc group composed of equal members of**
 - **HTA representatives (HTA Network, EUnetHTA JA3)**
 - **Regulators (STAMP, HMA, EMA)**

- * **1st Meeting, 26 June 2017, Brussels**

Ad Hoc Synergy Objectives

kick-off meeting

- to provide a snapshot in time of the work carried out by various fora, by mapping the actions (on-going and/or planned) of each of the participating fora relevant to the activities identified in the Reflection Paper in order to create synergies and avoid duplication and uncertainty in the work of HTA and regulatory bodies.
- to facilitate more contacts and interactions between different actors to contribute to the common objective of facilitating access to medicines.
- to suggest the best way forward in specific areas identified in the Reflection Paper.

Ad Hoc Synergy STAMP comments

Pre-Marketing

Collaboration area

Definition of
Unmet Medical Need
Therapeutic Innovation

Horizon scanning

Promotion of research and
dialogue in therapeutic areas
with unmet medical need

STAMP contribution

To promote discussions aiming at
bridging /combining various views &
aspects, in the context of **PRIME,**
CMA, AA

To promote discussions/efforts
reinforcing timely **publication of**
clinical trials results

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Ad Hoc Synergy STAMP comments

Market – entry

Collaboration area

Early information exchange on novel pharmaceuticals

STAMP contribution

To promote supporting activities in the context of **Compassionate Use**

Other areas

Initiative on patient involvement

To encourage/enable patients involvement in the discussions about unmet medical need, therapeutic innovation