# Health technology assessment
# - update -

**DG SANTE**

**Unit B4 – Medical products: safety, quality, innovation**

STAMP meeting, 14 March 2017

Health

European Commission

# Outline

1. Public consultation on the initiative for strengthening EU cooperation on HTA
2. Follow-up of the adoption of the Reflection Paper on synergies between regulatory and HTA issues
3. Next steps

European Commission

# Public consultation on EU cooperation on HTA beyond 2020

- Closed end of January 2017
- Number of contributions: 249
  - 63 individual/citizens
  - 186 non-individual: industry (52%), public administration (14%), patients and consumers representatives (13%).
  - Confirmed the issues identified in the Inception impact assessment
  - Substantiated both advantages and shortcomings of the current cooperation based on projects and joint actions
  - Overall support for continuation of EU cooperation beyond 2020 (93%)
- Publication of report: 2nd quarter of 2017

European Commission

# Reflection Paper on synergies between regulatory and HTA issues (1)

- **Aim:** To identify activities along the life-cycle of health technologies in which cooperation between regulatory and HTA bodies can contribute to facilitating efficient access to effective, safe, innovative, and added value technologies.
  - On-going and new activities
  - To be addressed in both short and medium/long term
  - Focused on pharmaceuticals
- Drafting WG: 9 MS + EMA
- STAMP and HMA provided input
- **Unanimously adopted by the HTA Network in November 2016**

European Commission

# Reflection Paper – Follow-up (2)

# Ad-hoc Synergy Group

- Suggested and agreed by HTA Network as follow-up mechanism
- "Ad hoc" coordination mechanism
- Equal numbers of HTA representatives (i.e. HTA Network and EUnetHTA JA3) and regulators (i.e. STAMP, HMA, EMA).

- **Objectives:**

  - To map the actions identified in the Reflection paper (on-going or planned by different fora), in order to create synergies and avoid duplication and uncertainty;

  - To facilitate contacts/interactions between different fora 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.

European Commission

# Reflection Paper – Follow-up (3) Ad-hoc Synergy Group

## Composition

- Approx.10 experts
  - 5 HTA representatives: HTA Network (DE, FR, IT, PT, UK) and EUnetHTA
  - 5 regulators' representatives: STAMP (2), HMA (2), EMA (1)
- Chaired by the Commission.

## Output

- A document outlining the mapping of actions relevant to the topics identifies in the Reflection Paper.

- A final report to the Commission including proposals for the next steps to further improve synergies between regulatory and HTA issues

# Reflection Paper – Follow-up (4)
# Ad-hoc Synergy Group

**Proposed organisation of work**

- Election of Rapporteur
- E-meetings + maximum two face to face meetings in Brussels
- Additional work via e-mail.

Members of the Group will have to report back to their respective organisations ensuring that discussions and conclusions of the Synergy Group are reflected in the on-going activities of each organisation.

European Commission

# Next steps

**STAMP nominations for the Synergy Group by 28 March**

Ref. Ares(2016)6599082 - 24/11/2016

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**

European Commission

# Thank you!

http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm