



HTA Network Working Group

**Process, aims and content of
Draft Reflection paper on
"Reuse of Joint Work in
national HTA activities**

The HTA Network Working Group

Set up **on 29 October** with **mandate:**

- “[...] to develop a draft reflection paper on the conditions **to facilitate take up and reuse at national level of HTA production**, including information and joint assessments (“Joint Work”)”

MSs volunteered:

- **Bulgaria, the Netherlands, Slovakia, Croatia, Sweden, Norway, Germany, Spain, Austria, Belgium, Portugal, Hungary and Italy**
- **France** (by the HTA Network) **as Chair**; **Croatia as Rapporteur** (by the HTA Network WG)
- **EUnetHTA** was invited to join the WG; **EMA was kept informed**; **Stakeholders** were planned to be invited ad hoc to share their experiences (EFPIA was invited at WG meeting on January 26)

Three meetings (December 16; January 26; February 16)

- *Suggestions and agreement on topics, content and the structure for the Reflection paper*

The main objectives of the reflection paper

In line with the HTA Network Work programme and the EU strategy on HTA cooperation, to provide recommendations on:

- ***How Joint Work shall develop, to facilitate its re-use in national/regional HTA activities***
- ***How national/ regional HTA authorities could address some of the facilitating factors to support reuse of Joint Work in national/regional HTA activities***
- ***How to facilitate re-use of national/regional work produced in another country/region***

A tool for HTA authorities and bodies to support their activities, both at national and at European level

To contribute to the development and design of the forthcoming JA on HTA

Structure of the document

Three chapters:

- **1. Background – WHY "re-use"**
- **2. Joint Work - WHAT to re-use – RECOMMENDATIONS** on how Joint Work shall develop to make it easier for national and regional HTA bodies to re-use it in national activities: **mainly addressed to HTA bodies, in their efforts to facilitate European cooperation (ie EUnetHTA)**
- **3. Joint Work - HOW to re-use – RECOMMENDATIONS** on how to address barriers to re-use of Joint Work in national and regional HTA activities: **mainly addressed to HTA authorities and bodies, in their national /regional HTA activities**

Background – WHY "re-use"?

- *Building on "**facilitating factors**" identified by the **HTA Network Strategy**, on the **experience gained within EUnetHTA Joint Actions**, the **SEED project** and **other cooperation efforts** in the area of HTA*

*A general consideration to the **Medical Device sector***

- *difficult at this stage to identify concrete mechanisms of cooperation for specific activities with the regulators of the sector as the European Legislation is currently under revision*
- *to be reassessed once the new legislation is in place*

Recommendations shall not interfere with Member States's competence in deciding on the implementation of Health Technology Assessments conclusions and **shall not harmonise any laws or regulations** of the Member States and **shall fully respect the responsibility of Member States** for the organisation and delivery of health services and medical care (Art 15.7 of Directive 2011/24)

"Joint work" (JW) - WHAT to re-use

- ***Joint Assessments Reports***
 - **Rapid Relative Effectiveness Assessments**
 - **Full/Comprehensive HTA**
- ***Tools***
 - The **HTA Core Model** (important for Joint Assessments Reports and national/regional assessment reports)
 - **Submission templates** (important for Joint Assessments Reports and national/regional assessment reports)
 - **Methodological standards for HTA**
 - **Training material**
 - **ICT tools** (including Databases, web based solutions etc.)
- ***Support of (initial and additional) Evidence Generation initiatives appropriate for HTA purposes***
 - **Early Dialogues**
 - **Coordination of additional evidence generation**

"JOINT WORK" (JW) - HOW TO RE-USE

- *How national/ regional HTA bodies could address some of the factors which may facilitate the **reuse of Joint Work** and the **reuse of national/regional work performed by other bodies***
- *Respect national responsibilities of Member States and their HTA Bodies to define their national/regional legal framework and working practices for implementing HTA*
- *Exclude aspects related to pricing and reimbursement issues*

Joint Work could be more often and better used in national /regional activities, if certain factors are addressed

- **1) Legal** (i.e. evidence requirements written in legal ordinance rather than submission templates); **2) Organisational** (i.e. process, time, resources) and **3) Scientific** (i.e. methodological challenges)