RAPID HTA: PRODUCING JOINT ASSESSMENTS ON PHARMACEUTICAL TECHNOLOGIES

WORK PACKAGE 5 STRAND A

Objective, Products and Output

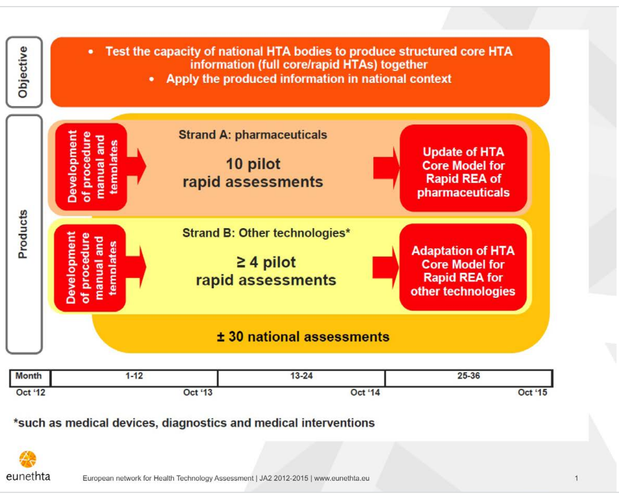

Figure 1: WP5 Overview

Topics

There are two main models for topic selection for rapid Relative Effectiveness Assessments for pharamceuticals (REAs) of pharmaceuticals:

Model 1: Suggestions from WP5 members. List from Committee for Medicinal Products for Human Use (CHMP): medicinal products currently under evaluation. This list is consulted with WP5 members and suitable pharmaceuticals are selected based on member preference.

Model 2: Expression of Interest from Manufacturer: The manufacturer has a suitable pharmaceutical that is currently in the MA evaluation process. The manufacturer contacts the coordination team and submits an offlcial expression of interest.

Who

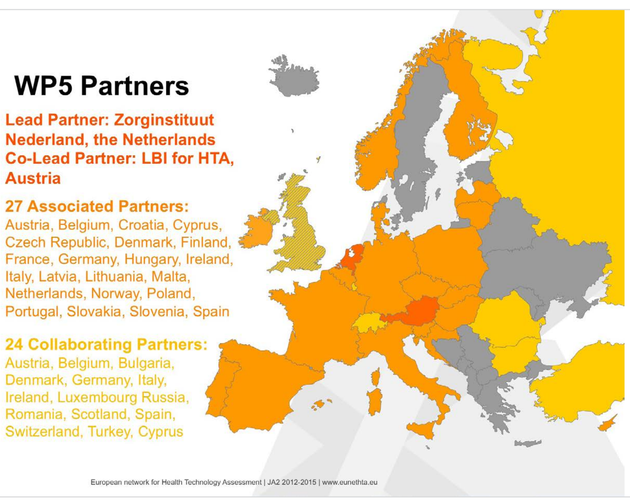

Figure 2: Participants in EUnetHTA

How

The main tools used for the production of standardized and high quality assessments are:

- the HTA Core Model for Rapid Relative Effectiveness of Pharmaceuticals
- the submission flle template for
- pharmaceuticals
- the project plan template
- the assessment templat

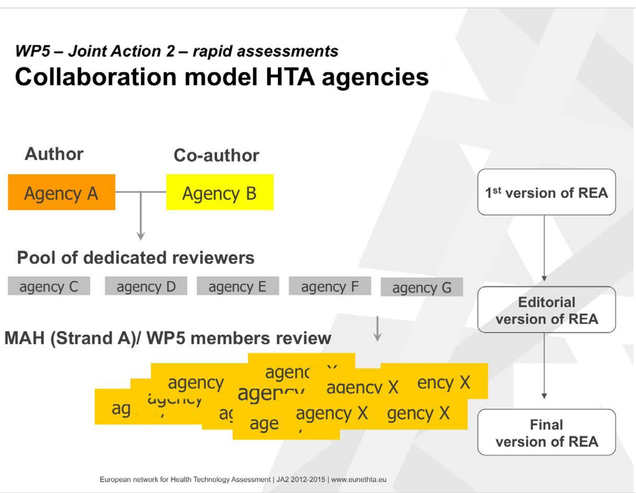

Figure 3: Collaboration process for REAs

9 Guidelines

1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life
6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison
8. Internal validity
9. Applicability.

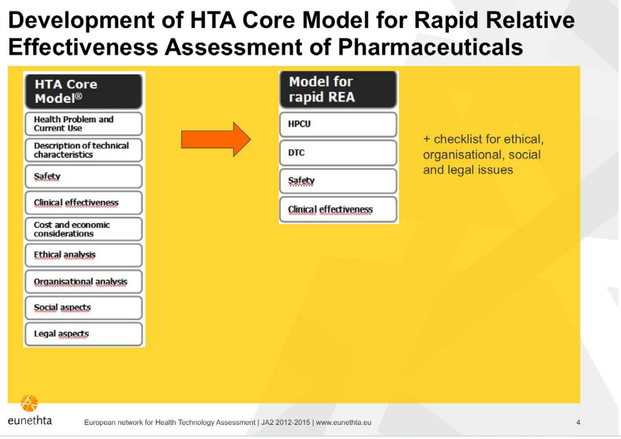

Figure 4: "Chapters" (i.e. domains) of the Full HTA Core Model and the HTA Core Model for Rapid Relative Effectiveness

Production process

Two main phases can be distinguished during the rapid REA production process:

- Scoping Phase: Includes the expression of interest from the MAH, the scoping meeting and the draft submission flle. Ideally, this phase occurs prior to the expected opinion of the CHMP.
- Assessment Phase: Includes the production of a REA draft, the review by dedicated reviewers, and the consultation of the REA editorial version with the MAH and the WP5 Members. Ideally, the REA is published shortly after the EPAR.

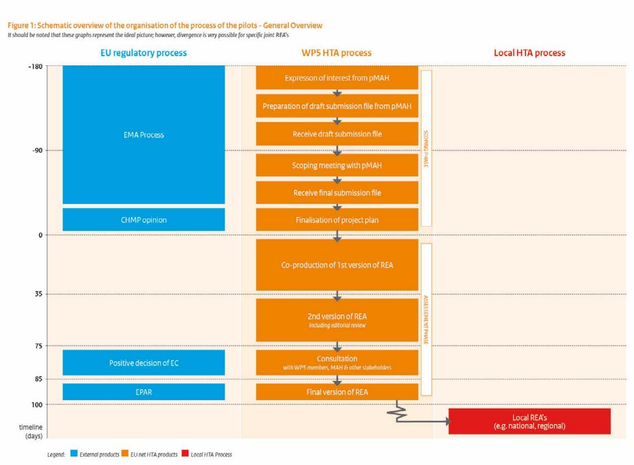

Figure 5: General Overview of the pilot procedure

No Recommendations

It is important to note, that the assessments do not contain speciflc recommendations. Decisions on Reimbursement have to be made at the local level.

First Pilot: Zostavax

Zostavax for the prevention of herpes zoster and post herpetic neuralgia

- Author: ZIN (Netherlands)
- Co-Author: "A. Gemelli" Teaching Hospital (Italy)
- Dedicated Reviewers: HAS (France), GOG (Austria), MoH Czech Republic, DPA/MFH (Malta), RIZIV (Belgium), MSSSI (Spain), Regio Veneto (Italy)
- Duration: 04/2013- published on the EUnetHTA website on 08/2013
- Uptake or use in local/national reports: Austria (twice, 2013), Spain (2013), Netherlands (2014), France (2014)
- 5 more reports are planned

http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/Zostavax_main%20report%20including%20appendices_20130922.pdf

Second Pilot: Canagliflozin

Canagliflozin for the treatment of type II diabetes mellitus

- Authors: AAZ (Croatia), FIMEA (Finland) Regione Veneto (Italy)
- Dedicated Reviewers: HAS (France), HVB (Austria); CAHIAQ (Spain); Medical University of Sofia (Bulgaria); MoH Czech Republic
- Duration: 05/2013 -02/2014
  - Delay mostly due to external factors (i.e. delayed opinion of CHMP)
- Local reports:
  - Netherlands, Croatia, Finland
  - 7 more are planned

http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/WP5_SA-2_canagliflozin_for_the_treatment_of_diabetes_mellitus.pdf

Ongoing and planned REAs

- Third REA: Ongoing
  Scoping Meeting held in September 2014
  Expected start of Assessment Phase in October 2014
- Fourth REA: Ongoing
  Scoping Meeting held in October 2014
  Expected start of Assessment Phase in November 2014
- Fifth REA: Planned
  Pilot team complete
  Expected start of Scoping Phase in December 2014

Local/National usage of Rapid HTA

Examples of usage include:

1. Translation of the whole rapid assessment into national language and the format of local/national HTA agencies.
2. Direct use of the Rapid HTA: Using the rapid HTA directly to inform discussions on the use of the technology.

More EUnetHTA members are or will be using already published assessments in their own local/national context. However, only until the end of 2015 more precise information on the actual usage and thus on efflciency gains will be available.

Outlook

The updated version of the HTA Core Model for Rapid Relative Effectiveness is currently under review by EUnetHTA members.

The Scientiflc Advisory Group and the Public will get the opportunity to comment on the draft version prior to its flnalization. The planned date for these activities is in summer 2015.

Further Information

The different applications of the HTA Core Model can be found here: http://meka.thl.fl/htacore/BrowseModel.aspx

More detailed information on the production process of the rapid REAs of pharmaceuticals can be found in the current version of the Procedure Manual: http://www.eunethta.eu/outputs/wp5-strand-procedure-manual-v-3

For already published Rapid HTAs on other technologies, please visit the EUnetHTA website: http://www.eunethta.eu/

To contact the Coordinating Team responsible for the production of Rapid HTAs on pharmaceuticals, you can write to:

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