European network for Health Technology Assessment

Safe and Timely Access to Medicines for Patients (European Commission's STAMP expert group)

Brussels, May 6, 2015

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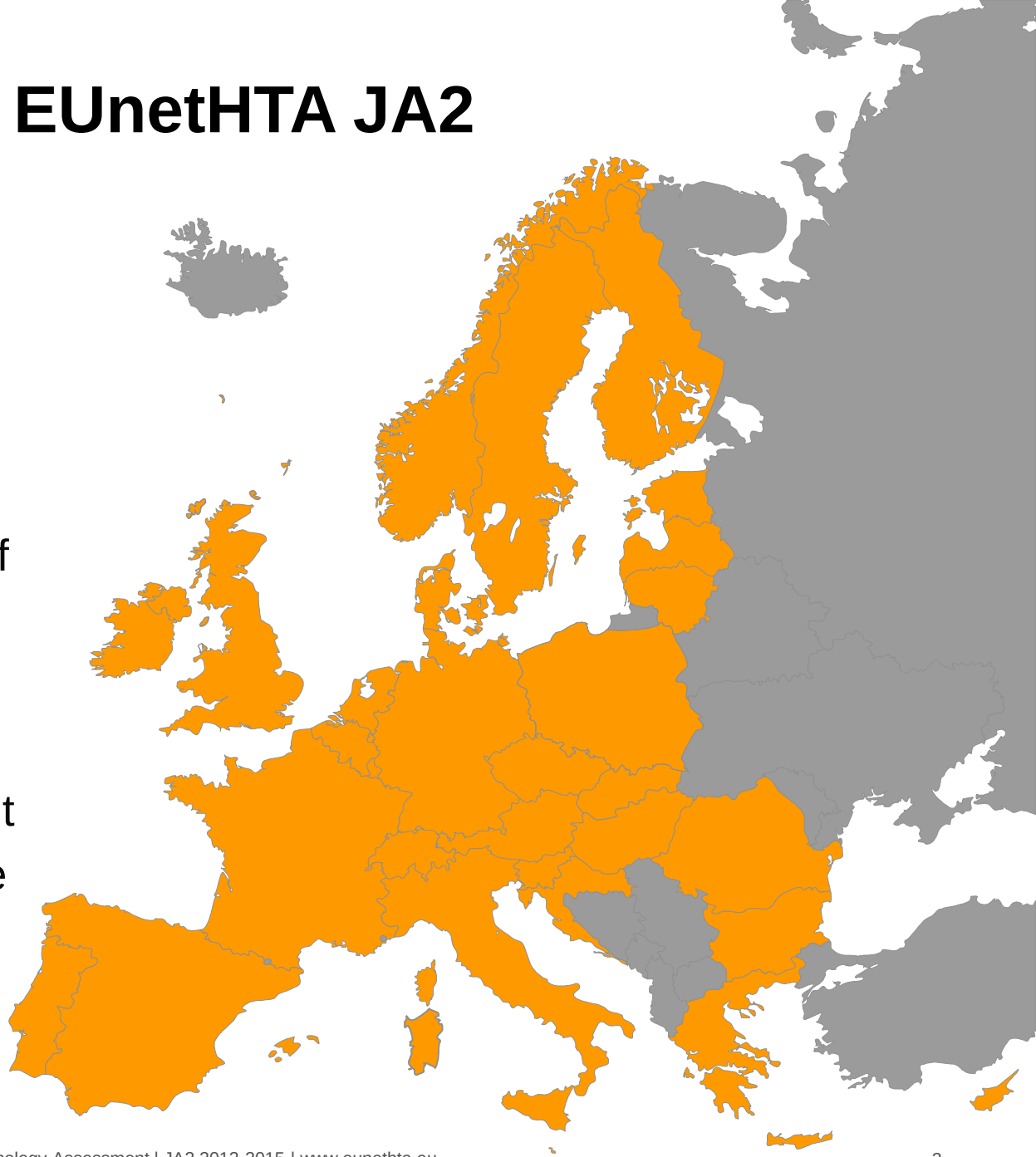
Chairman of EUnetHTA Executive Committee
Secretariat Director, EUnetHTA Secretariat
Danish Health and Medicines Authority, DHMA,
Copenhagen, Denmark

Participants in EUnetHTA JA2

EUnetHTA Partners and Associates

49 Partner organisations designated by Ministries of Health

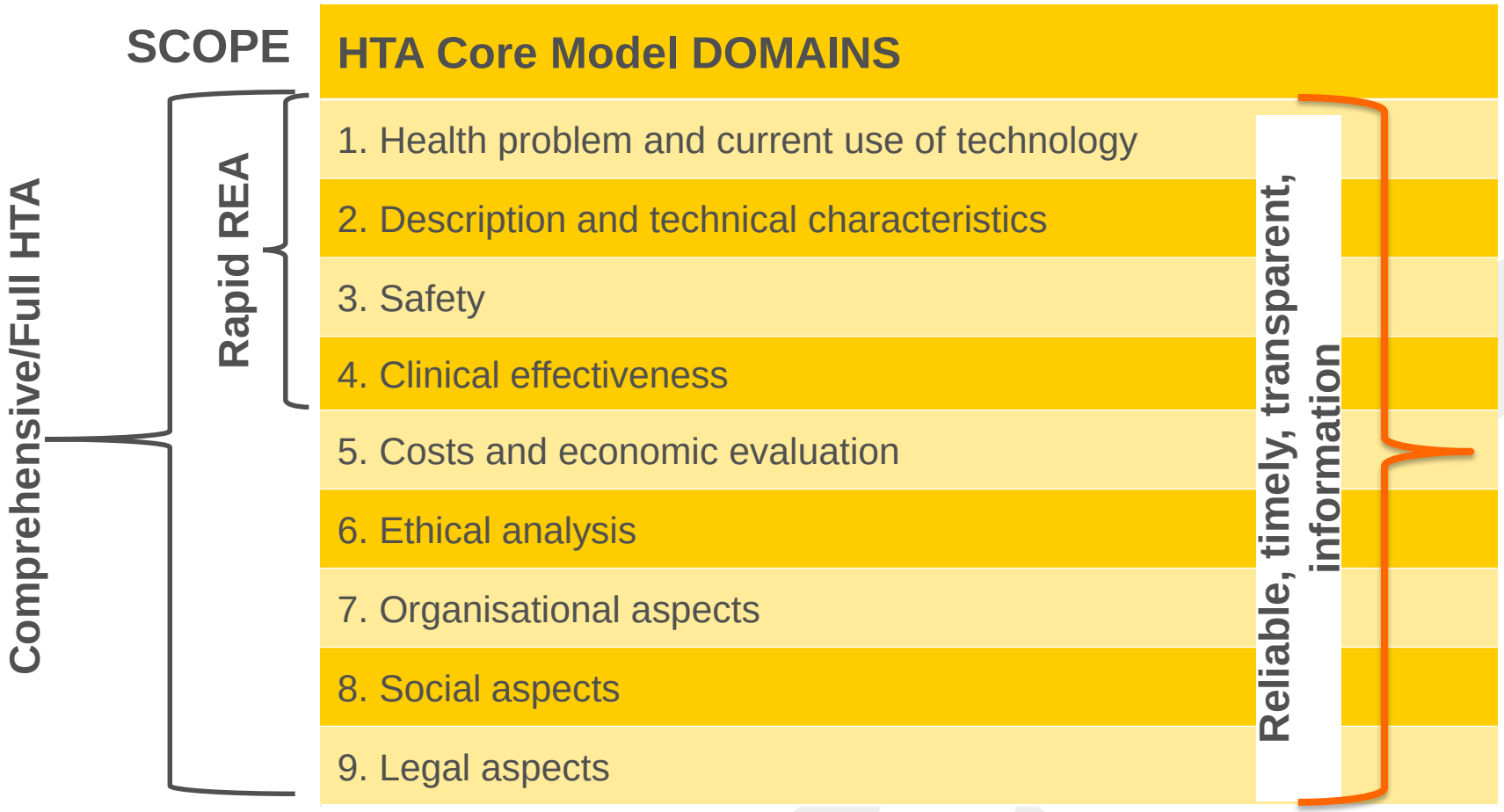
Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA



Some of the Partner Organisations in Joint Action 2 (2012-15), e.g.

- Germany, IQWIG,DIMDI (+GBA, Medical Valley – EMN)
- France, HAS
- UK, NICE, NETSCC (+HIS Health Improvement Scotland)
- Italy, AGENAS, AIFA, ASSR Emilia Romagna, Veneto Region
- Spain, ISCIII, AETSA, OSTEBA, Avalia-T, AQuAS (Spanish HTA Network)
- Poland, AHTAPOL
- Sweden, SBU, TLV
- Croatia, AAZ, CHIF Croatian Health Insurance Fund
- Portugal, INFARMED
- Austria, LBI, GÖG, HVB, Danube University Krems, UMIT
- Netherlands, ZIN
- Belgium, KCE, INAMI Institut National d'Assurance
- Bulgaria, NCPHP, NCPRMP, Medical University of Sofia
- Finland, THL, FIMEA
- Denmark, DHMA (Coordinator), CFK Region Midt; KORA

The Domains of the HTA Core Model® - assessing dimensions of value



EUnetHTA Tools

HTA Core Model Online

HTA Core Model for Rapid Relative Effectiveness

Submission template (undergoing piloting)

Planned and Ongoing Projects Database (POP)

Evidence database on new technologies (EVIDENT)

Adaptation Glossary & Toolkit

Contact Database

Intranet Groups

E-meeting facility

News Aggregator

WP5 – Joint Action 2 – Where are we now?

First pilot

- Zostavax for prevention of Herpes Zoster (Sanofi-MSD), author organisations: ZIN (NL) and A. Gemelli (Italy). Published Sept. 2013

Second pilot

- Canagliflozin for treatment of diabetes type 2 (J&J), author organisations: FIMEA (Finland), AAZ (Croatia) and Regio Veneto (Italy). Published Feb. 2014

Third pilot

- sorafenib for advanced thyroid carcinoma (Bayer), author organisations: AIFA (Italy) and IMFARMED (Portugal). Published March 2015

Fourth pilot

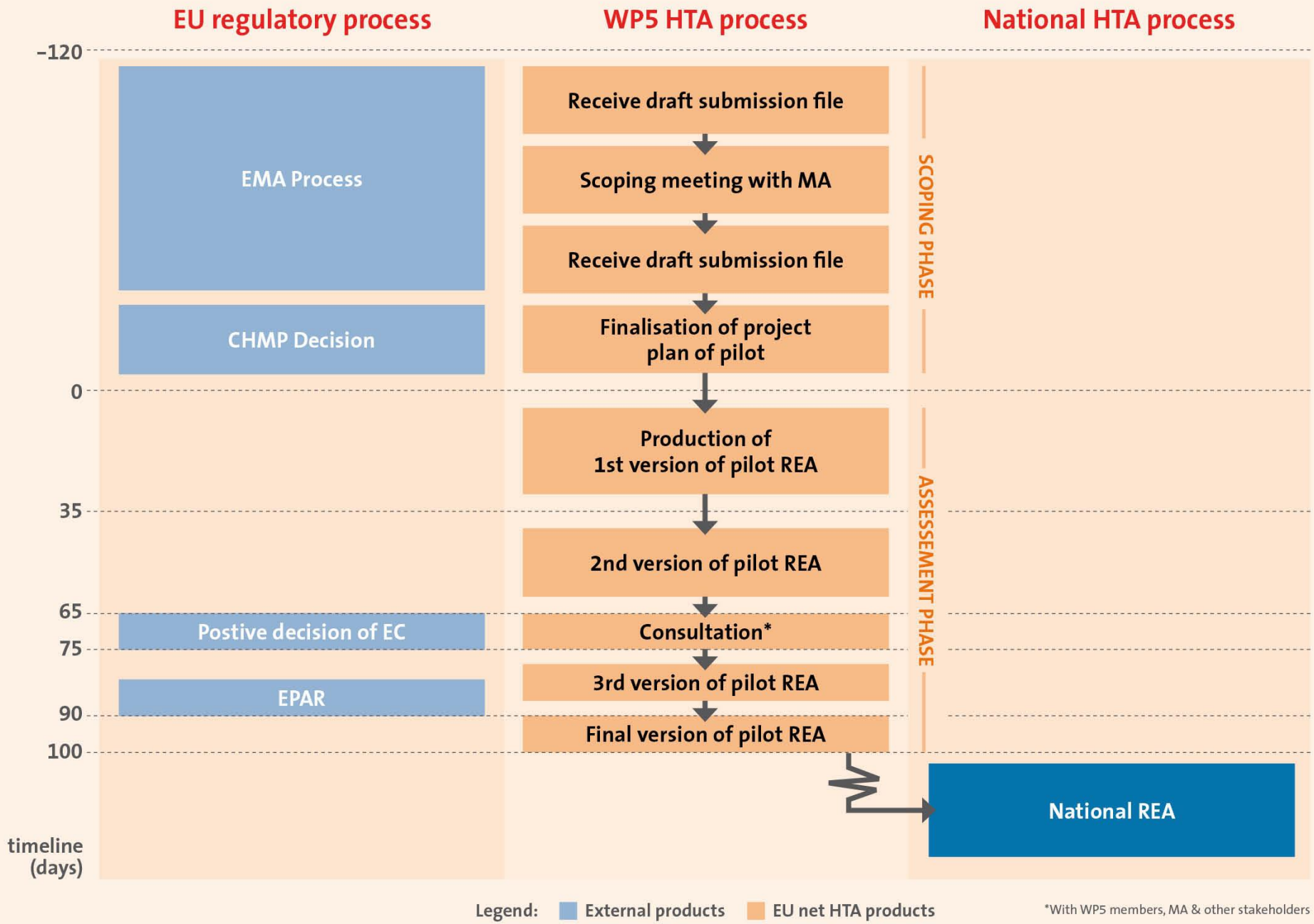
- ramucirumab in combination with paclitaxel for previously treated advanced gastric and gastro-oesophageal junction cancer (Eli Lilly), author organisations: NOKC (Norway) and AAZ (Croatia). Published March 2015

Fifth pilot

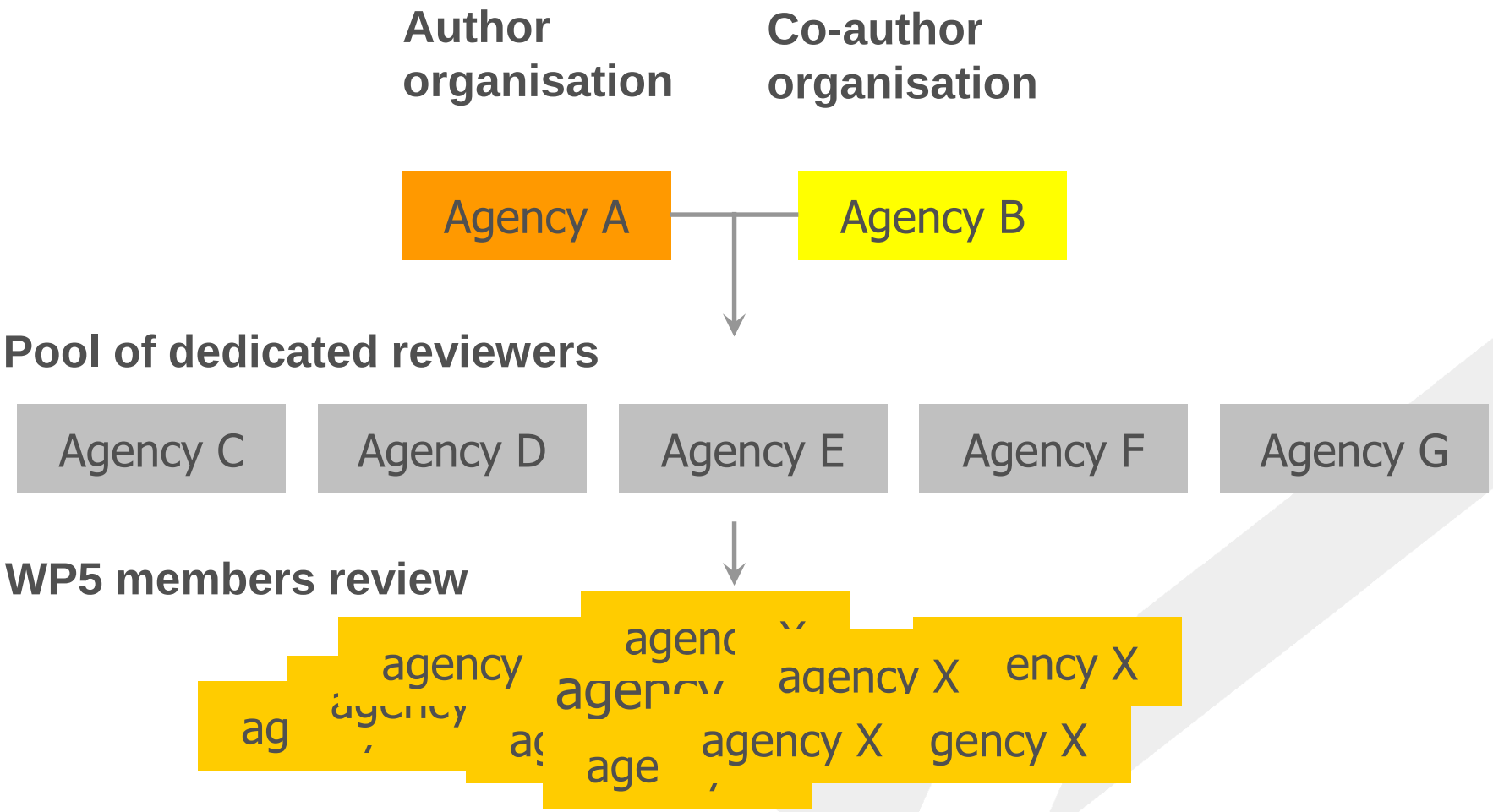
- Vorapaxar for cardiovascular complications after MI (MSD), author organisations: HAS (France) and Ministry of Health (Slovakia). Expected publication: June 2015

Sixth pilot

- New Hepatitis C treatments, author organisations: KCE and RIZIV (Belgium), HVB (Austria), AAZ (Croatia), A. Gemelli (Italy). Planned publication Dec. 2015


EU regulatory process
WP5 HTA process
National HTA process
-120
EMA Process
CHMP Decision
0
Receive draft submission file
Scoping meeting with MA
Receive draft submission file
Finalisation of project plan of pilot
SCOPING PHASE
Production of 1st version of pilot REA
35
2nd version of pilot REA
65
Postive decision of EC
Consultation*
75
3rd version of pilot REA
EPAR
90
Final version of pilot REA
ASSESSEMENT PHASE
100
National REA
timeline (days)
Legend:
External products
EU net HTA products
*With WP5 members, MA & other stakeholders

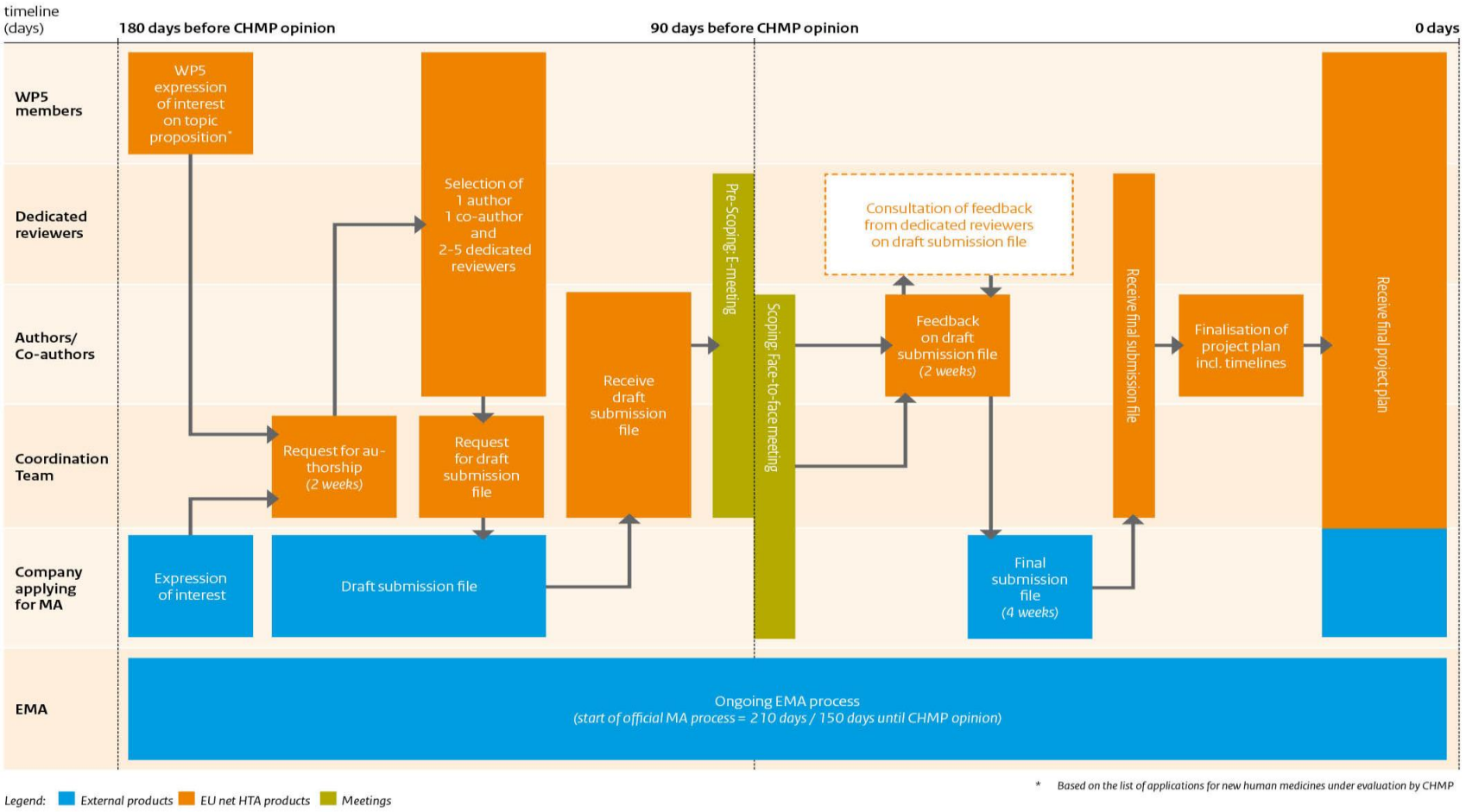
Organisation of Joint Assessments



WP5 Strand A – Scoping Phase

Figure 2: Schematic overview of the Scoping Phase

It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REA's



Scoping Phase

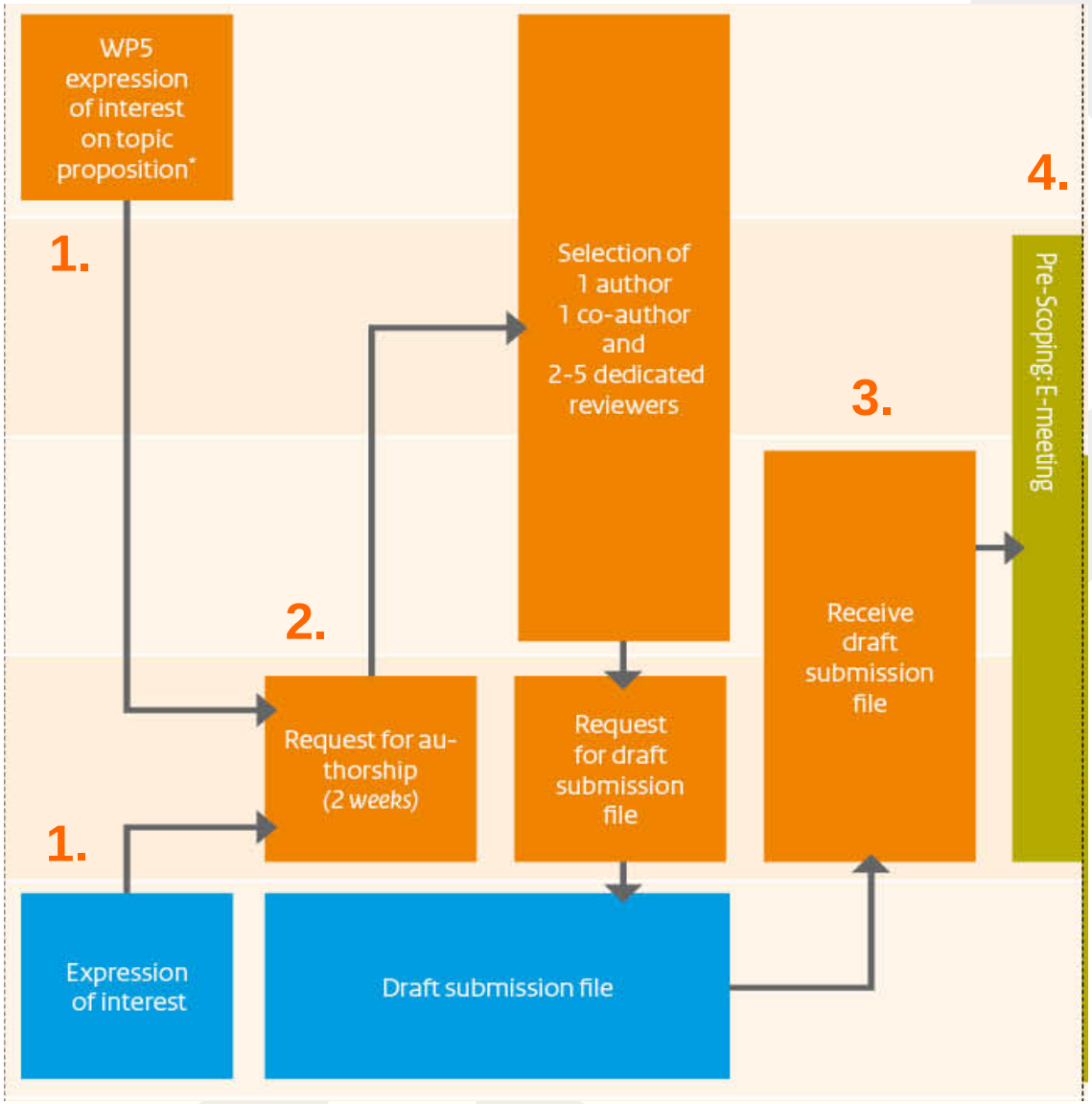
1. Expression of interest regarding topic by:

- ❖ Pharmaceuticals company
- ❖ HTA organisation (WP5 members)

2. Selection of Author/Co-Author organisation/ Reviewers (WP5 internal process)

3. Receive draft submission file from MAH

4. Pre-Scoping E-Meeting



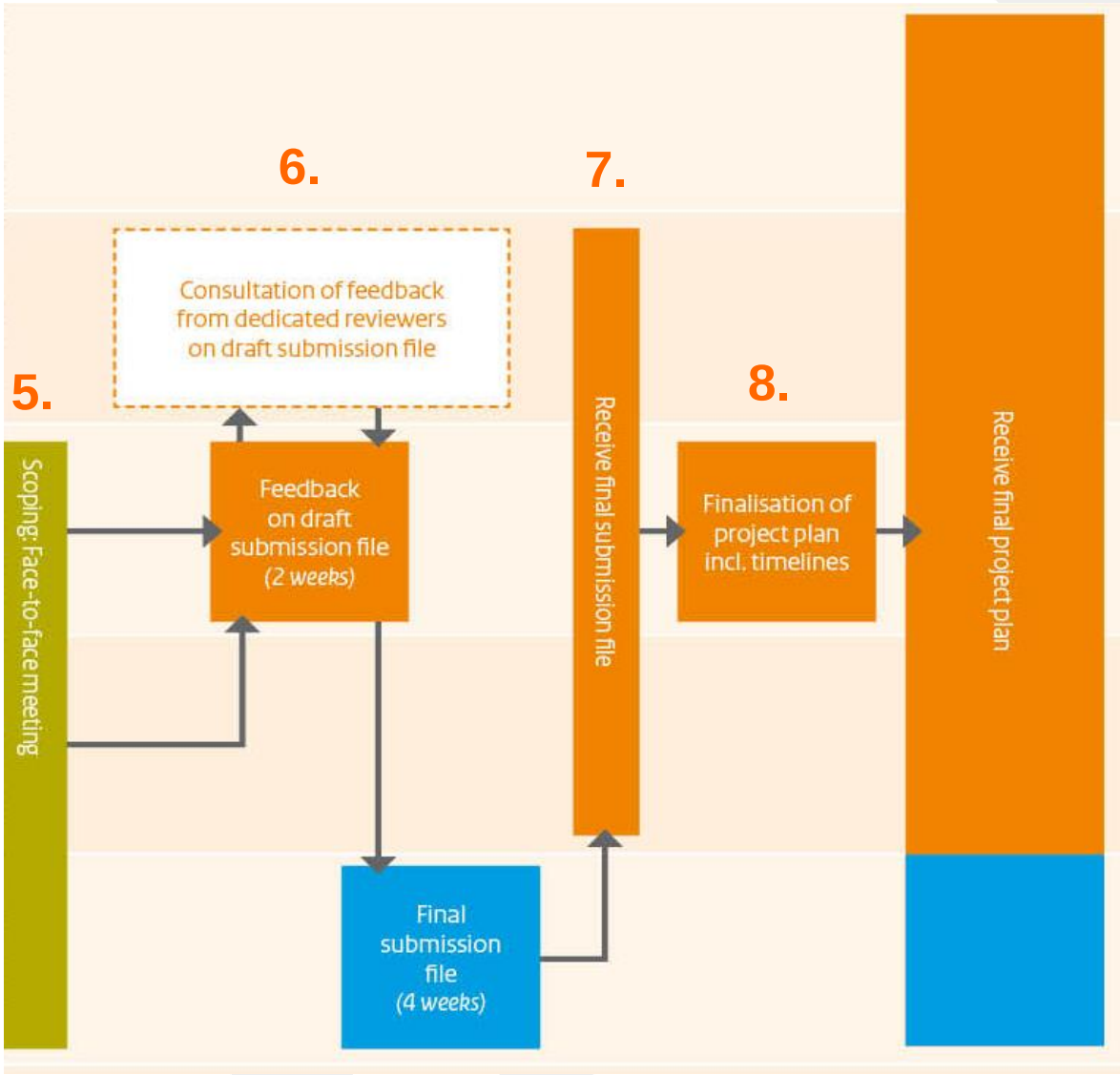
Scoping Phase

5. Scoping meeting with MAH (f-t-f)

6. Feedback from Author organisation on draft submission file

7. Receive final submission file

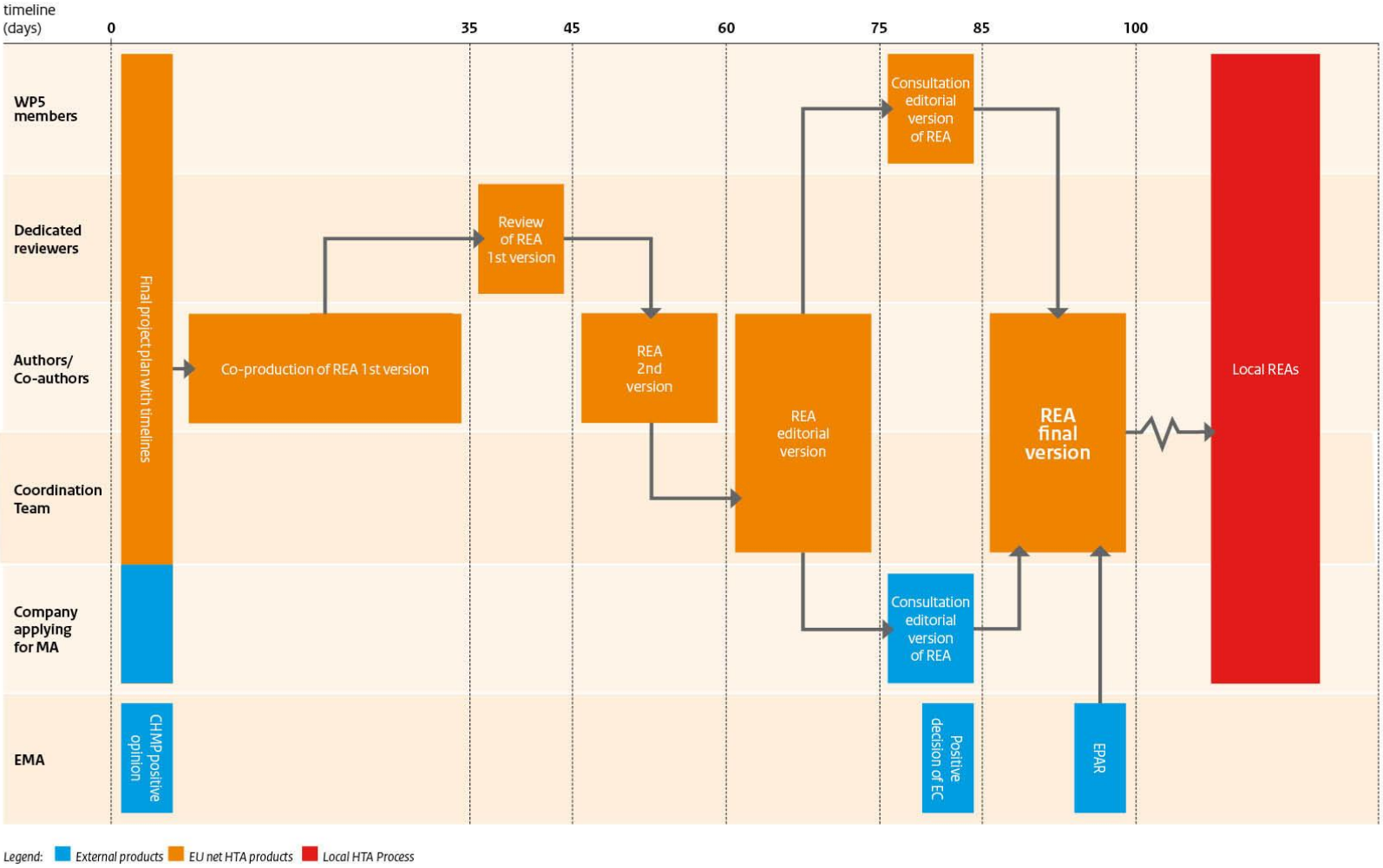
8. Finalisation of project plan including timelines



Assessment Phase

Figure 3: Schematic overview of the Assessment Phase

It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REA's

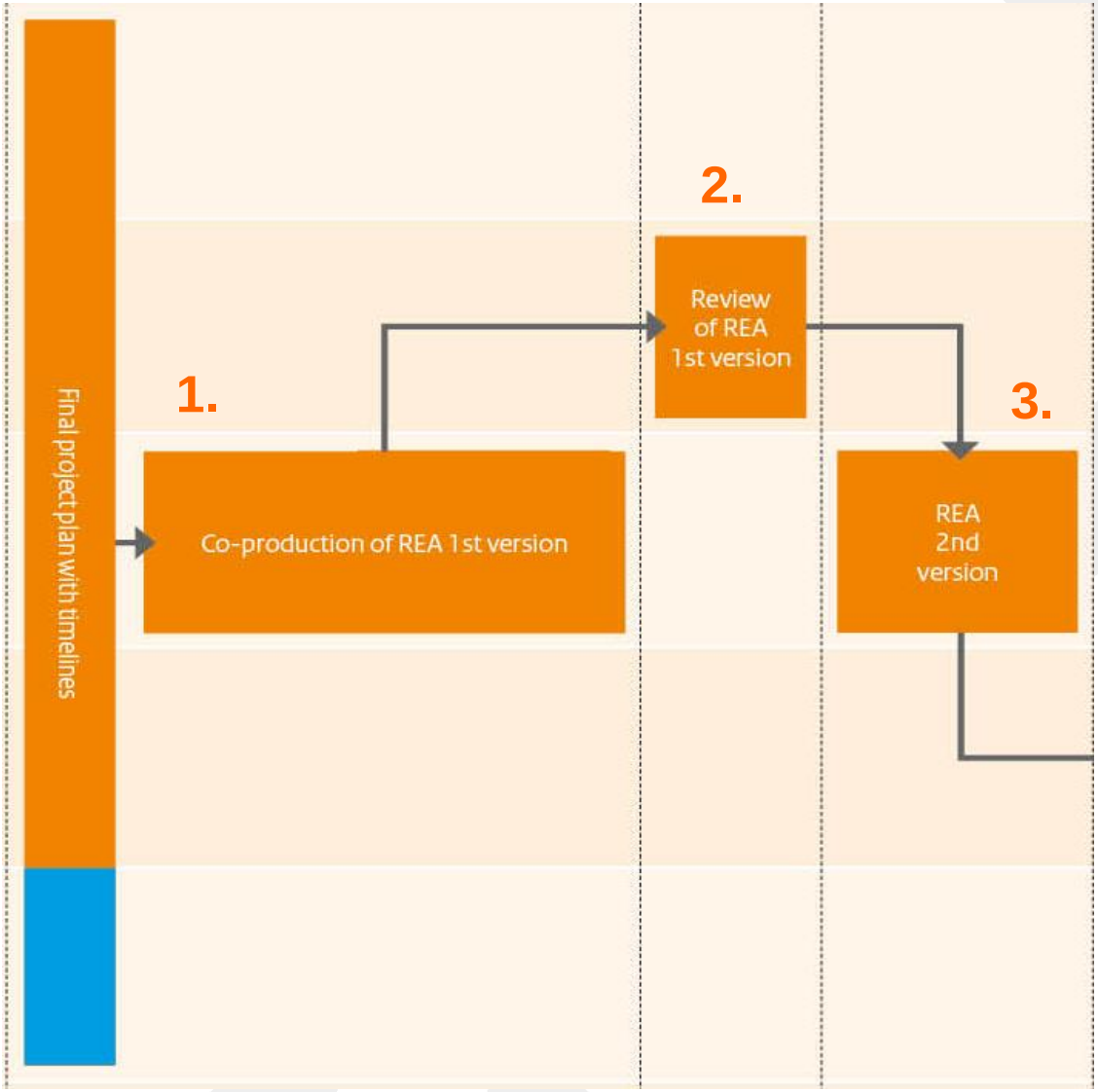


Assessment Phase

1. Preparing the first draft of the assessment by the Author organisation and Co-Author organisation (35 days)

2. Review by dedicated reviewers (10 days)

3. Preparation of second draft of the assessment by author organisations (15 days)



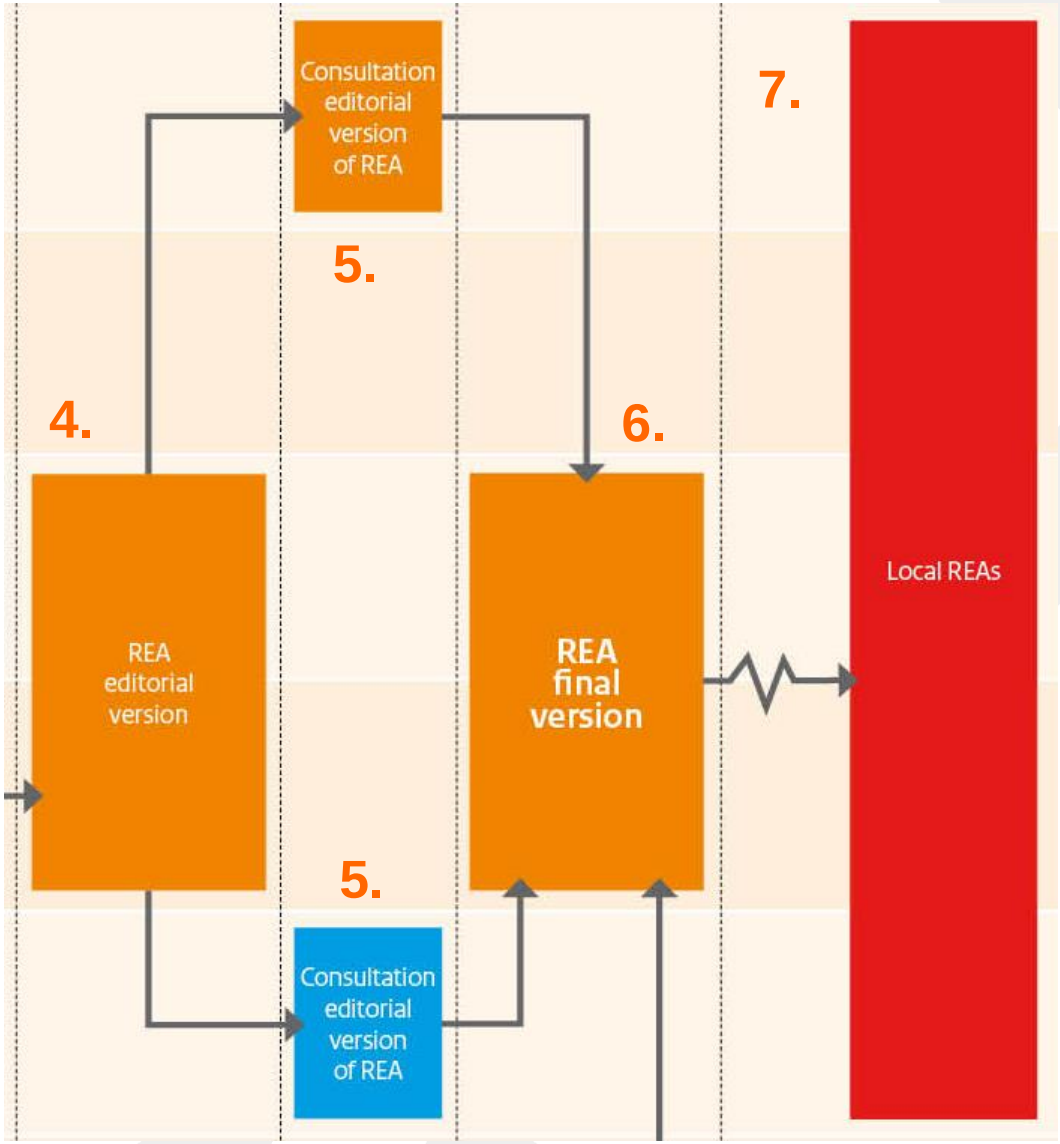
Assessment Phase

4. Editorial review and layouting (15 days)

5. Consultation phase of all WP5 members and market authorisation holder (10 days)

6. Final version of the assessment (15 days)

7. Publication of final report and implementation into the national context (optional)



Survey on outcomes of HTA of sofosbuvir across Europe*

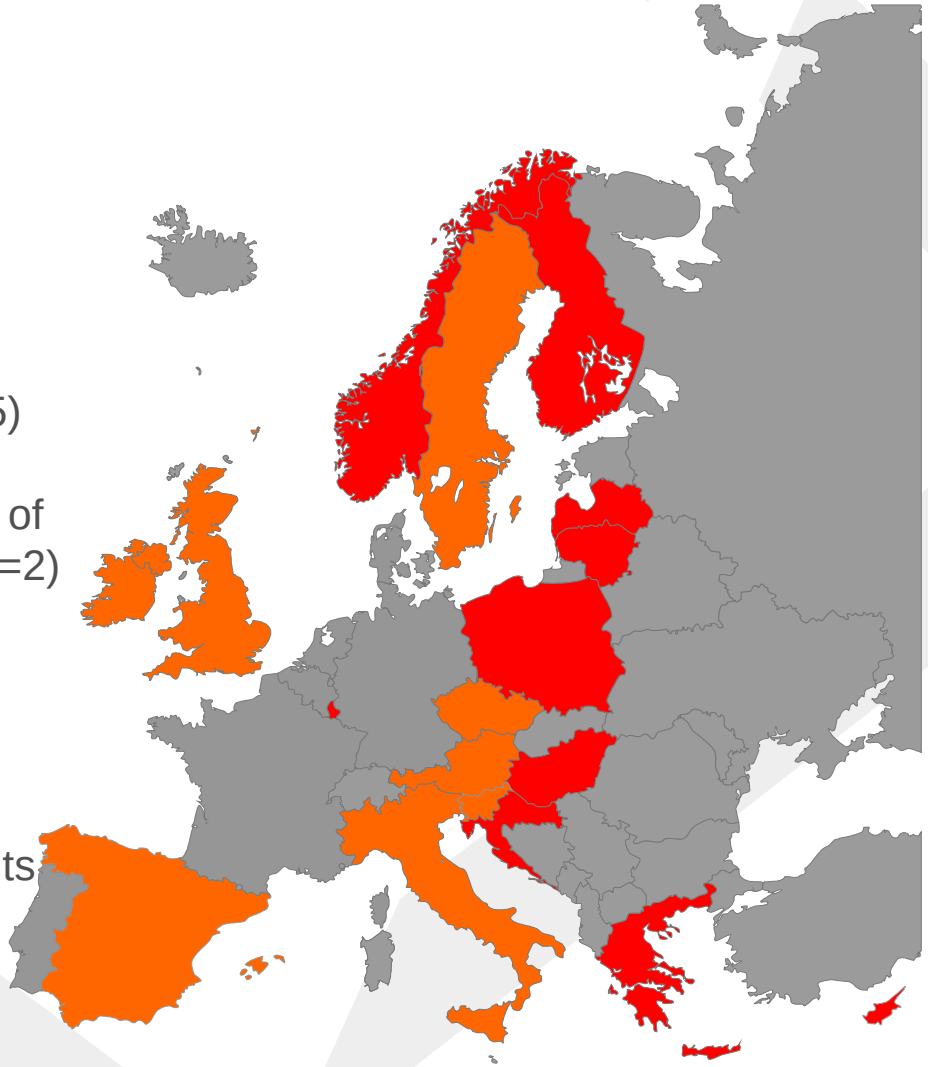
- questionnaires to EUnetHTA Partners and members of the Medicine Evaluation Committee (MEDEV) in 28 (30) countries
- information about
  - status of any assessment
  - final or preliminary assessment results on
    - clinical effectiveness
    - cost-effectiveness
    - budget-impact of sofosbuvir
  - reimbursement status
- willingness to share (preliminary) assessment report(s) on sofosbuvir

By early September 2014 28 responses were received from 26 countries

* Thanks to: Hedi Schelleman, Rudy Dupree, Finn Børlum Kristensen, Wim Goettsch

Survey results

- 26 out of 30 jurisdictions* responded
- 10 jurisdictions **no** assessment started
  - No application received (n=5)
  - No assessment needed
    - drug falls into the category of communicable diseases (n=2)
    - hospital drug (n=1)
  - Unknown (n=3)
- 9 countries assessment **ongoing**
  - Two jurisdictions provided interim results
    - Full report: England and Wales
    - No full report: Spain, Slovenia**



** EU plus Norway and Switzerland. For UK there were separate responses from England and Wales, and from Scotland. For Romania and Estonia no contact address was available N=28*

*** In Slovenia the assessment was done by National Viral Hepatitis Expert group*

Survey results

7 jurisdictions assessment **complete**

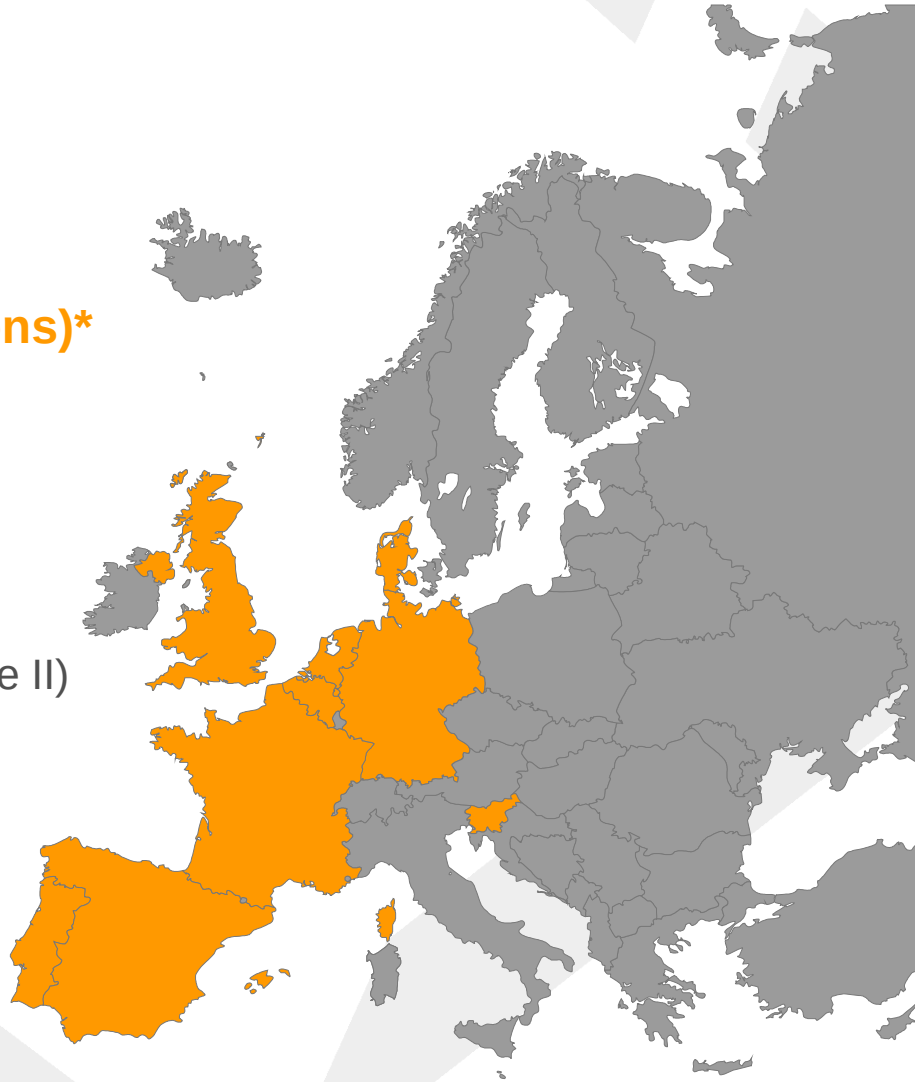
- Full report: Denmark; France; Germany (IQWiG and G-BA*); Netherlands; Scotland

- No full report: Belgium; Portugal

**IQWIG and G-BA do not make two separate assessments: IQWiG is commissioned by the G-BA to assess the manufacturer dossier's studies for the G-BA. The G-BA makes the final assessment for Germany after a hearing procedure consisting of written statements and an oral hearing with clinical experts, scientific medical societies and other stakeholders.*

Survey results

Data available: **full reports (6 jurisdictions)* and statements (4 jurisdictions)**



Sofosbuvir effectiveness data:

- 8 RCTs (**4 phase III** and 4 phase II)
  5 non-randomised studies (**2 phase III**, 3 phase II)
- > 1500 patients

The outcomes most mentioned in the reports:

- **SVR12: Sustained virological response 12 weeks after the end of treatment**
- QoL: Health-related quality of life
- Mortality
- **Safety**

**from one jurisdiction (Germany) there are two full reports (IQWIG and G-BA) available.*

Thank you

Any questions?

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme