

EUnetHTA

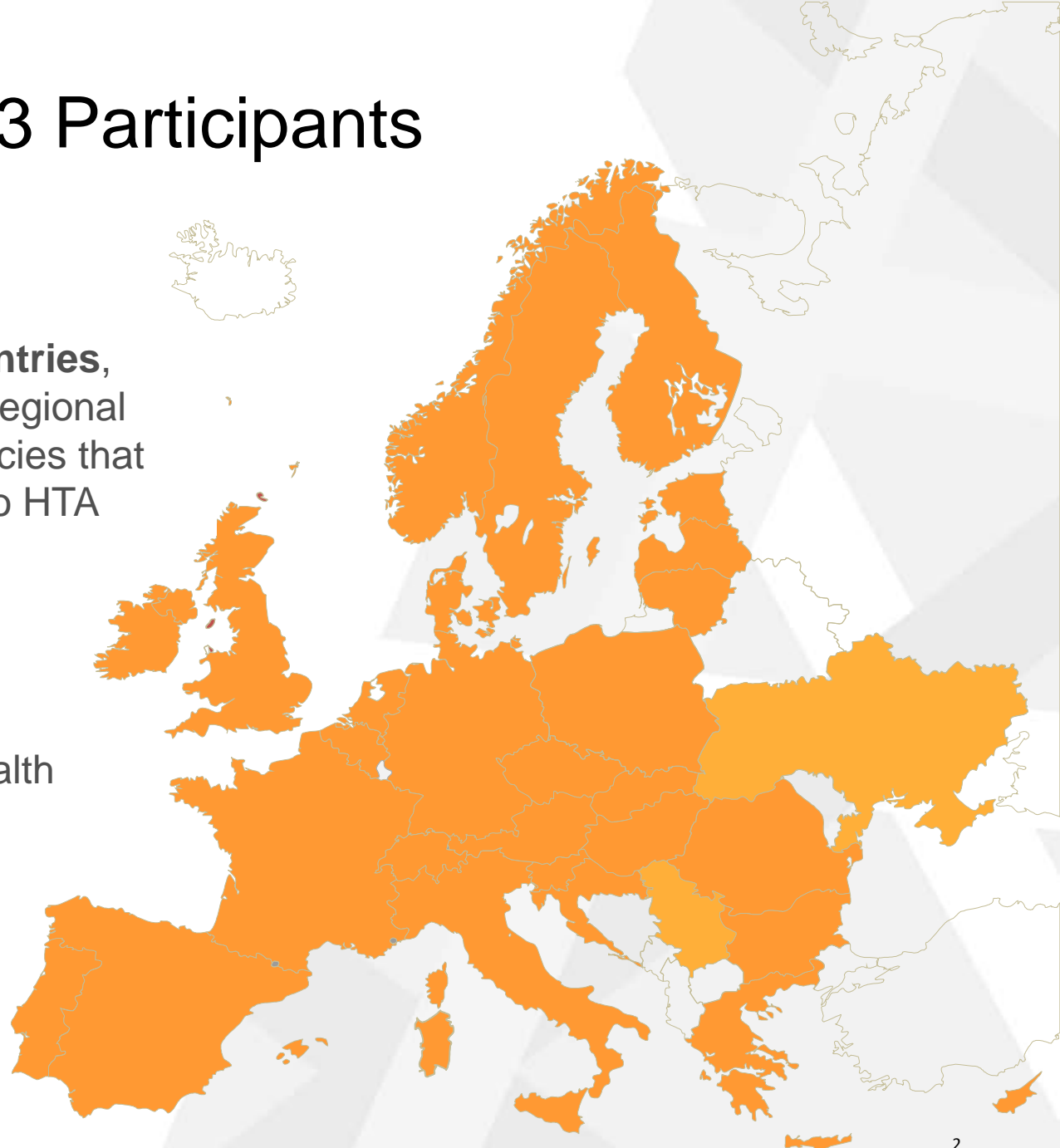
Joint HTA production

Marcus C. Guardian, Chief Operations Officer, EUnetHTA

EUnetHTA JA3 Participants

81 partners of 29 countries,
consisting of national, regional
and non-for-profit agencies that
produce or contribute to HTA

Project Coordinator:
The Dutch National Health
Care Institute (ZIN)



Joint Action 3 Objectives

Sustainable model for joint HTA work

Increase use, quality and efficiency of HTA

Increase
collaboration

Increase
production

Increase
usage

Sharing
knowledge

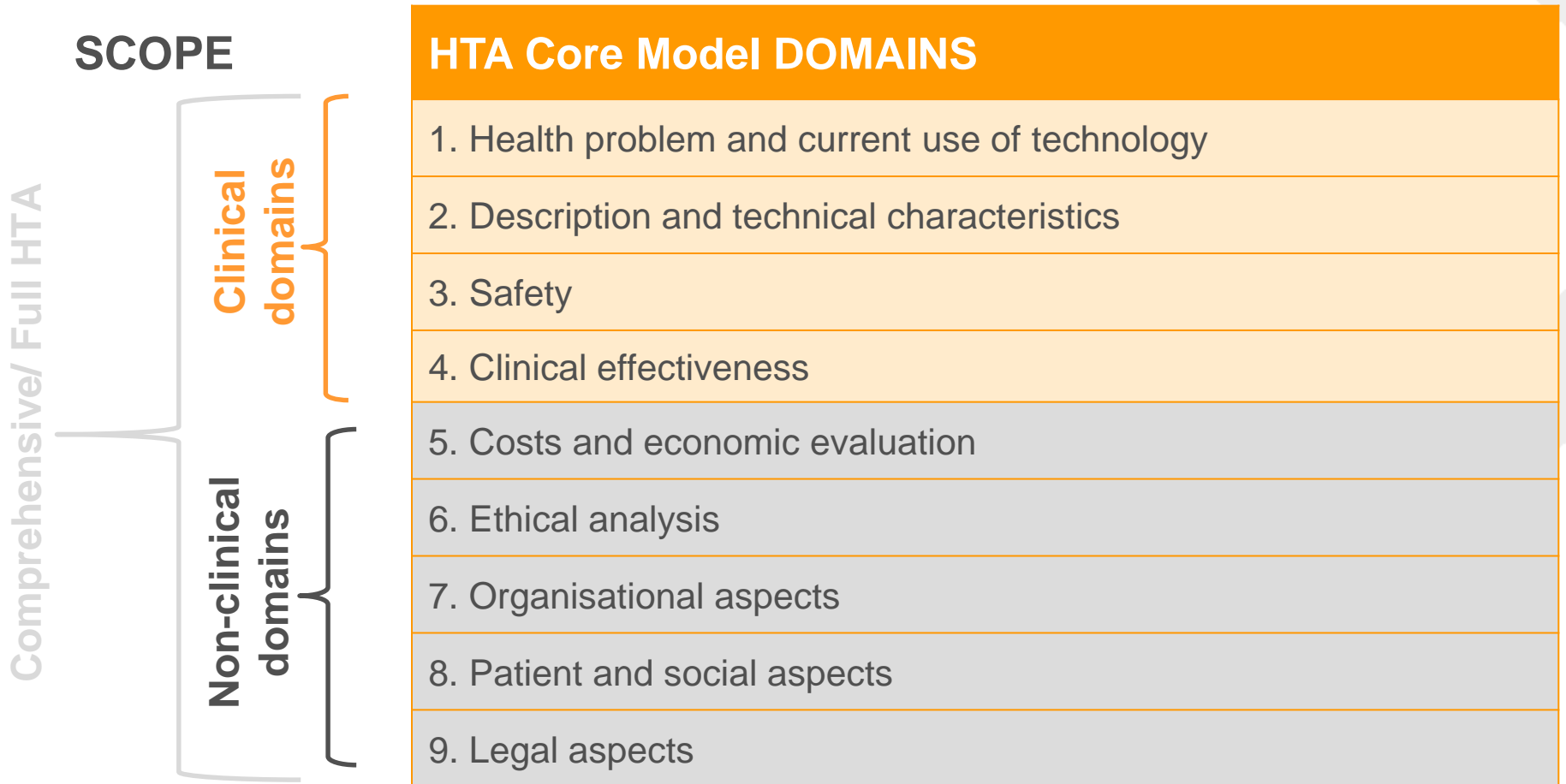
Alignment of
processes

Implementation

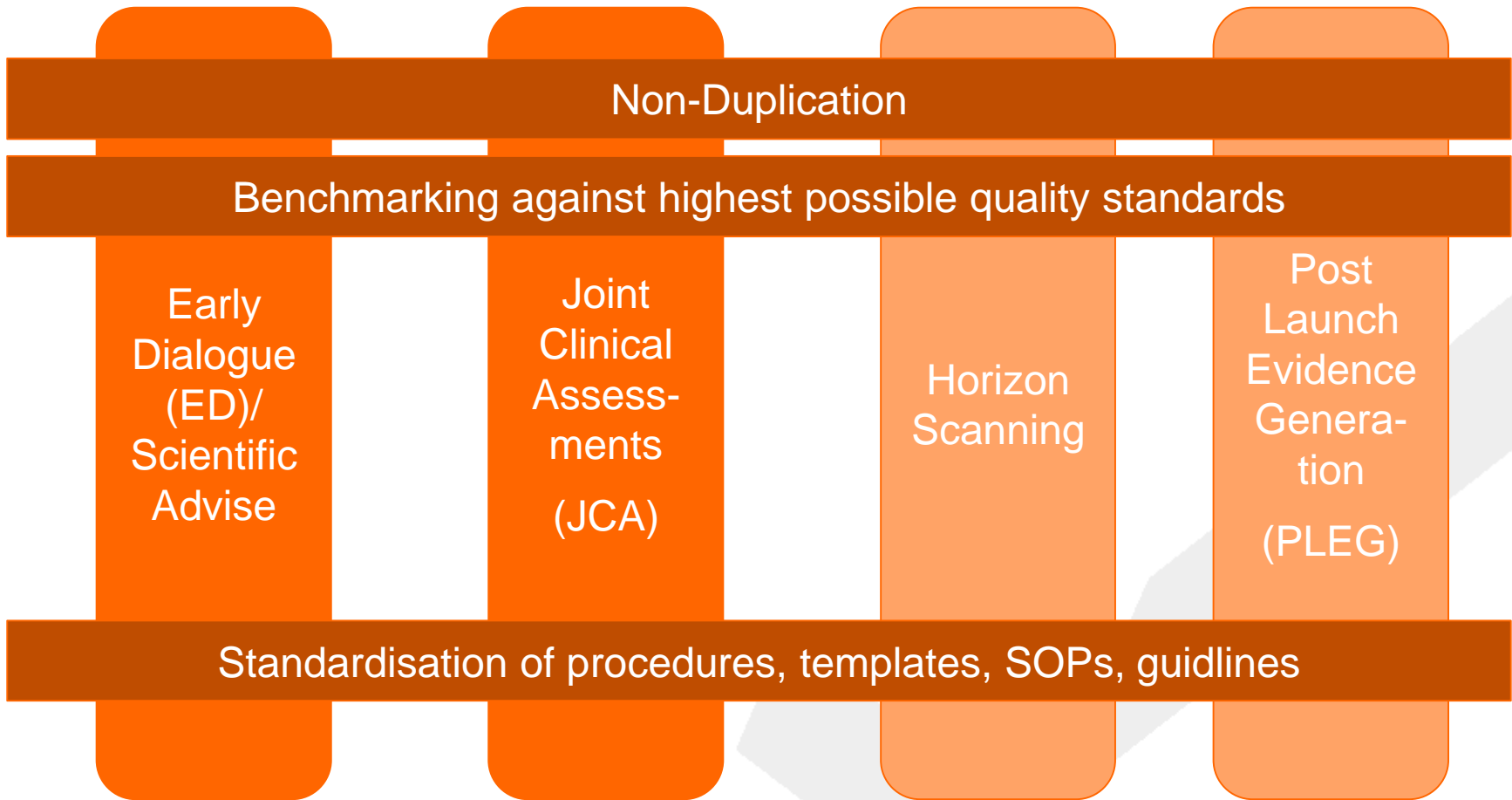
EUnetHTA Stakeholders



EUnetHTA HTA Core Model[®]

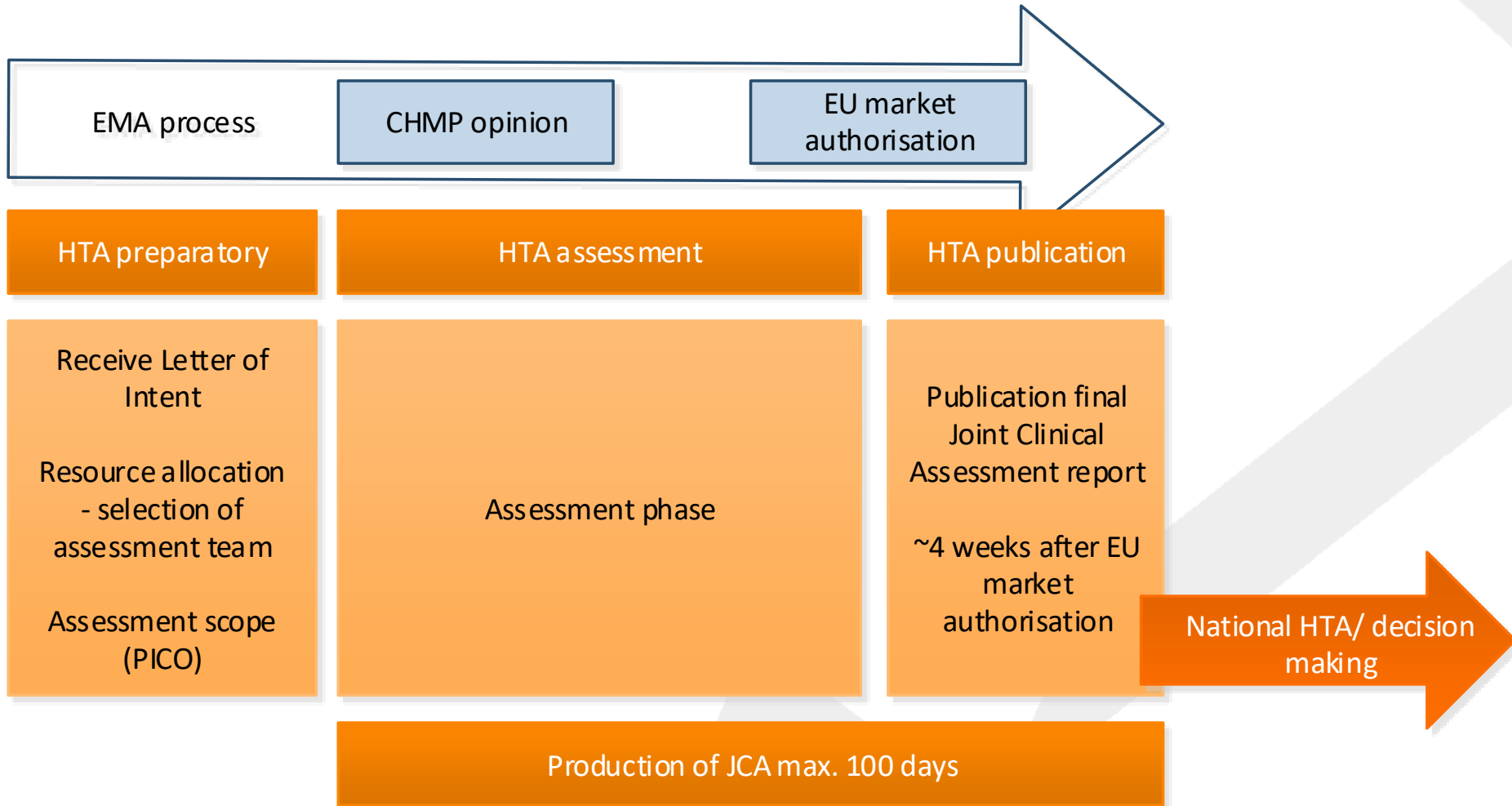


Joint HTA production



Thank you!

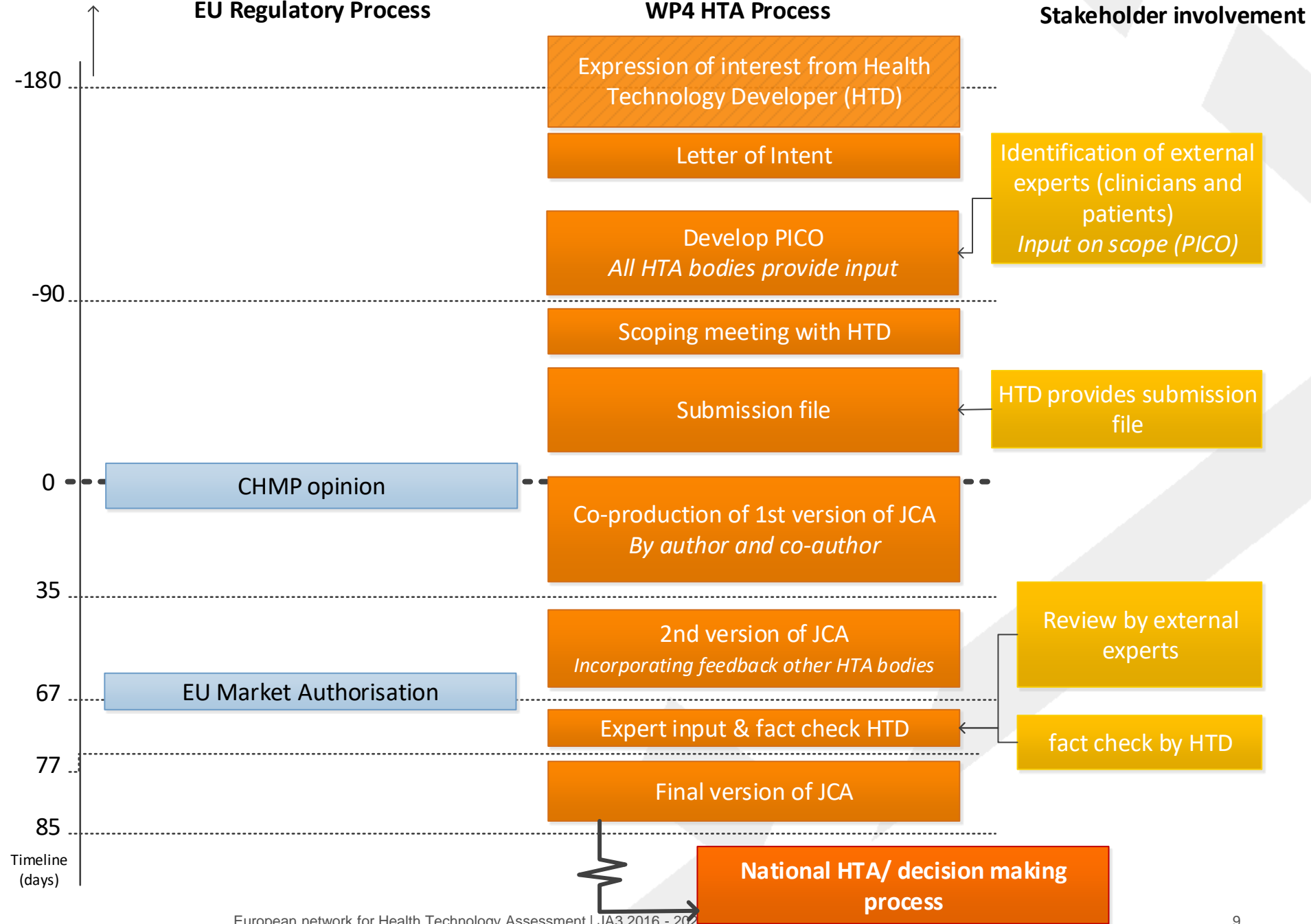
Timelines Joint Assessment dependent on CHMP



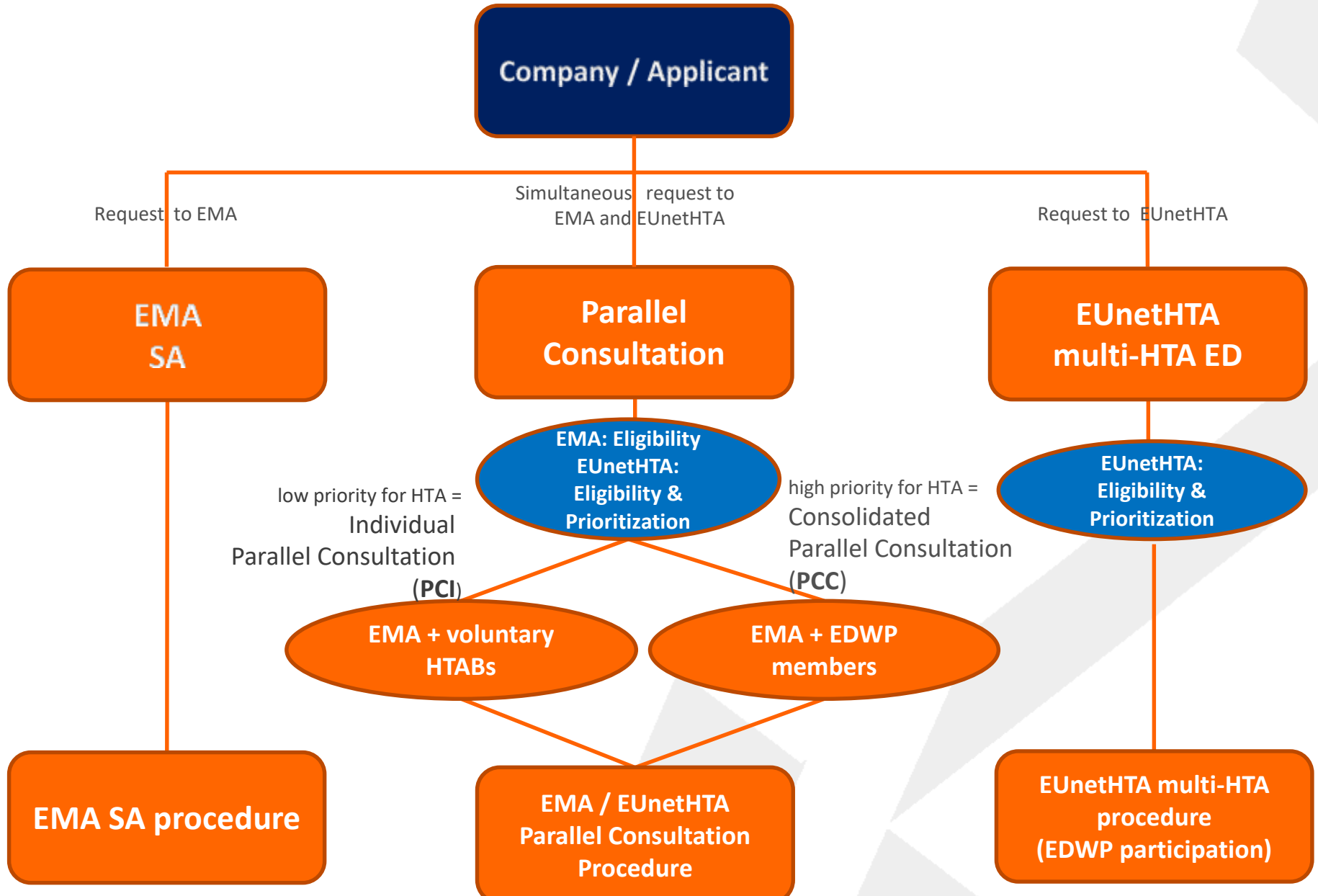
EU Regulatory Process

WP4 HTA Process

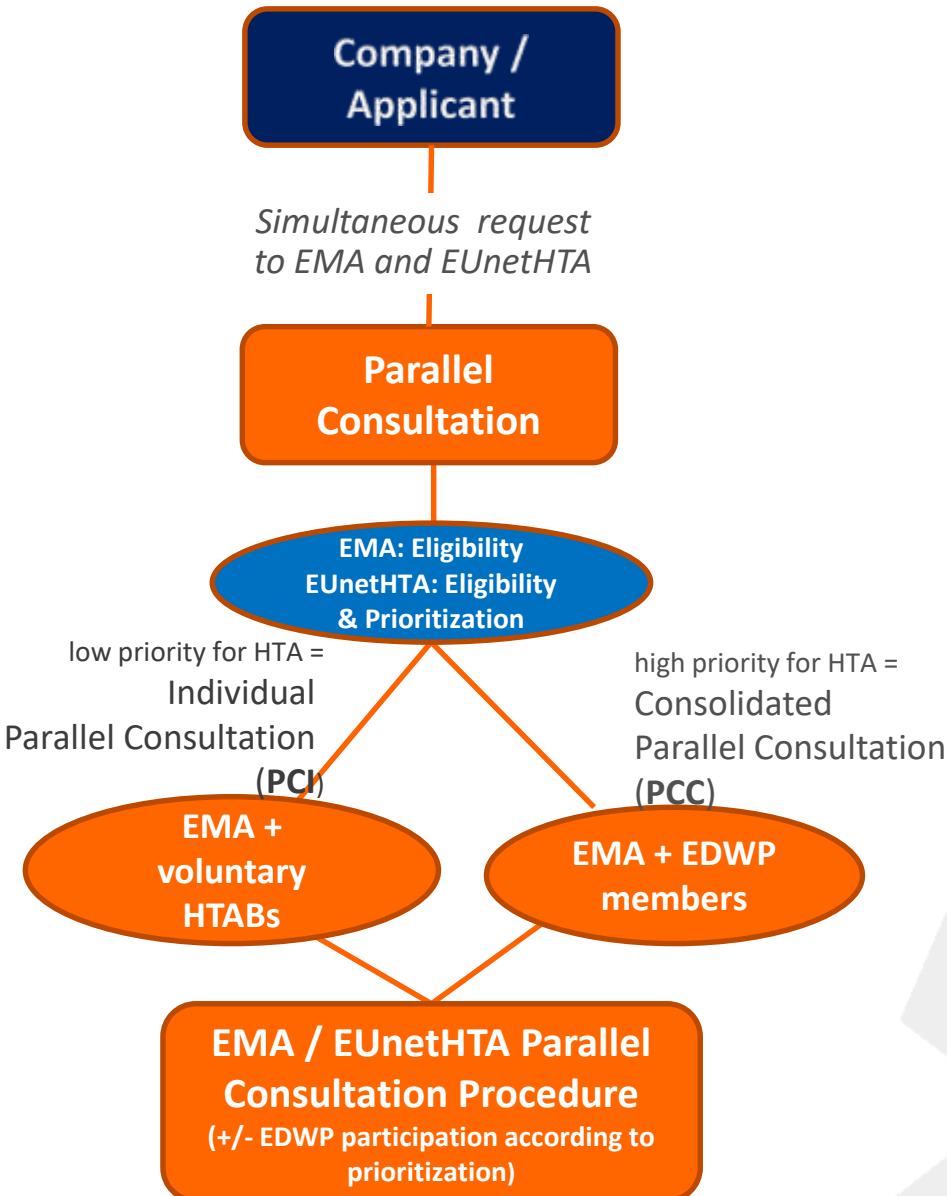
Stakeholder involvement



Early Dialogues



Early Dialogues



Parallel Consultations

One procedure, 2 pathways

- ▶ PCI - products NOT meeting EDWP selection criteria; not eligible for use of EUnetHTA budget (except for coordination tasks)
- ▶ PCC - products meeting EDWP selection criteria; EUnetHTA budget can be used (but some agencies may be financed with fees)

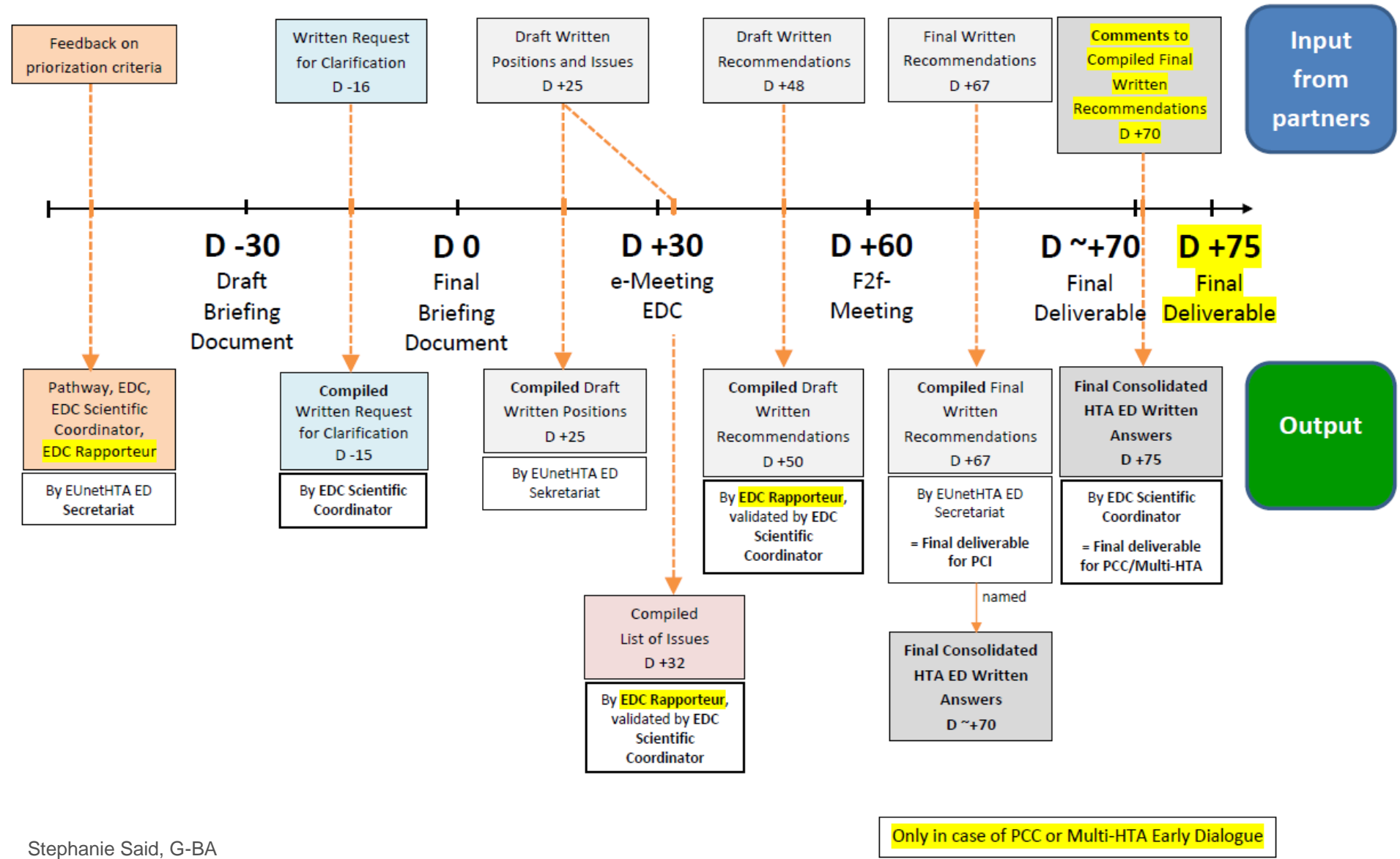
Clear priorities for the involvement of EDWP:

Prioritization criteria to target products aimed at bringing added benefit to patients, i.e.:

- New mode of action for the indication AND
- Targeting life-threatening or chronically debilitating disease AND
- Responding to unmet need

Timelines for one Early Dialogue

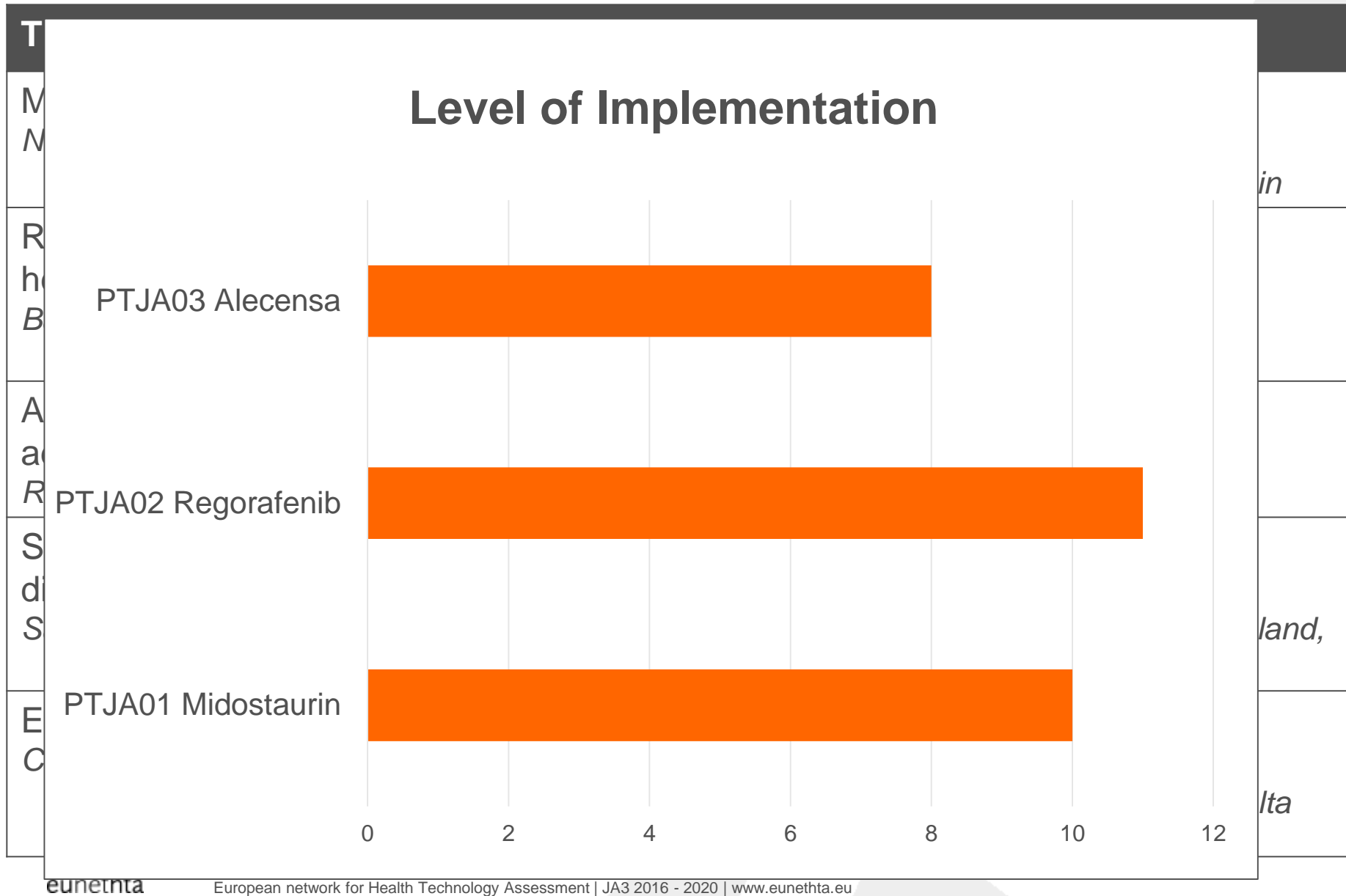
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Health Providers (HTA Network Stakeholders)

- Council of European Dentists (CED)
- European Association of Hospital Pharmacists (EAHP)
- European Forum for Primary Care (EFPC)
- European Hospital and healthcare Federation (HOPE)
- European Public Health Association (EUPHA)
- European Society of Cardiology (ESC)
- European Society of Medical Oncology (ESMO)
- European Union of General Practitioners/ Family Physicians (UEMO)
- Pharmaceutical Group of the European Union (PGEU)
- Standing Committee of European Doctors (CPME)

Pharmaceutical Joint Assessments



Uptake PTJA01 - Midostaurin

Country	Agency	Details of use
Italy	AIFA	Used for background information
Spain	AEMPS	Cited in the national report as background or additional information
UK (Scotland)	HIS	Used for validation of submission from the technology developer
Croatia	AAZ	A summary of the report was prepared in the national language, as well as assessment elements B0001 and A0020, with links to the full report on English language. Upon Croatian decision makers request on this topic, the report will be updated if needed and local information will be added (i.e. epidemiological information such as patient numbers; the technologies available in Croatia; information about costs;..), including recommendations
Spain	AETSA	A summary of this EUnetHTA assessment in Spanish together with the full English report has been published on AETSA's website for dissemination. In addition, the report has been distributed to the regional decision-makers and hematologists
UK	NICE	EUnetHTA reports are indexed in the NHS evidence, a public database which provides access to selected sources of evidence in health, social care and public health
France	HAS	Cited in the national report as background or additional information

Uptake PTJA02 - Regorafenib

Country	Agency	Details of use
Austria	LBI-HTA	National adaptation. Made no changes to the information used, added recommendations
France	HAS	The national report structure is partly based on the REA, especially for the EFF and SAF parts. Most of the references used in the TEC and CUR parts are also in the national report. Final REA was transmitted to the HTA committee members before the national assessment. Cited in the national report as background or additional information
Italy	AIFA	Efficacy and safety information used as supportive information in national report. Cited in the national report as background or additional information
Portugal	INFARMED	National adaptation, translated some sections of the REA for use in national report and added recommendations
Spain	AEMPS	Cited in the national report as background or additional information
UK (Scotland)	SMC	Used for background information
Croatia	AAZ	A summary of the report was prepared in the national language, as well as assessment elements B0001 and A0020, with links to the full report on English language. Upon Croatian decision makers request on this topic, the report will be updated if needed and local information will be added (i.e., epidemiological information; the technologies available in Croatia, costs), including recommendations
Spain	AETSA	A summary of this assessment in Spanish together with the full English report has been published on AETSA's website for dissemination. In addition, the report has been distributed to region decision makers and oncologists
UK	NICE	Used as background information to check that similar issues were being identified in national assessment. In addition, EUnetHTA reports are indexed in NHS Evidence, a public database which provides access to selected sources of evidence in health, social care and public health.