European HTA collaboration
Current status, future plans and relevance for the Netherlands

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Outline

- HTA and market access to medicines
- Reason for collaboration on HTA in Europe
- What is the current status of collaboration (EUnetHTA)
  - Joint Assessments
    - Current Joint Assessments (published)
    - Process / timelines and interaction with EMA
- Proposal for EC legislation after EUnetHTA (post 2020)
- Conclusions

HTA versus REA

- Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

HTA versus REA

- Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

- Relative effectiveness [assessment] (REA) can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

European collaboration on HTA

Technologies become more ‘international’

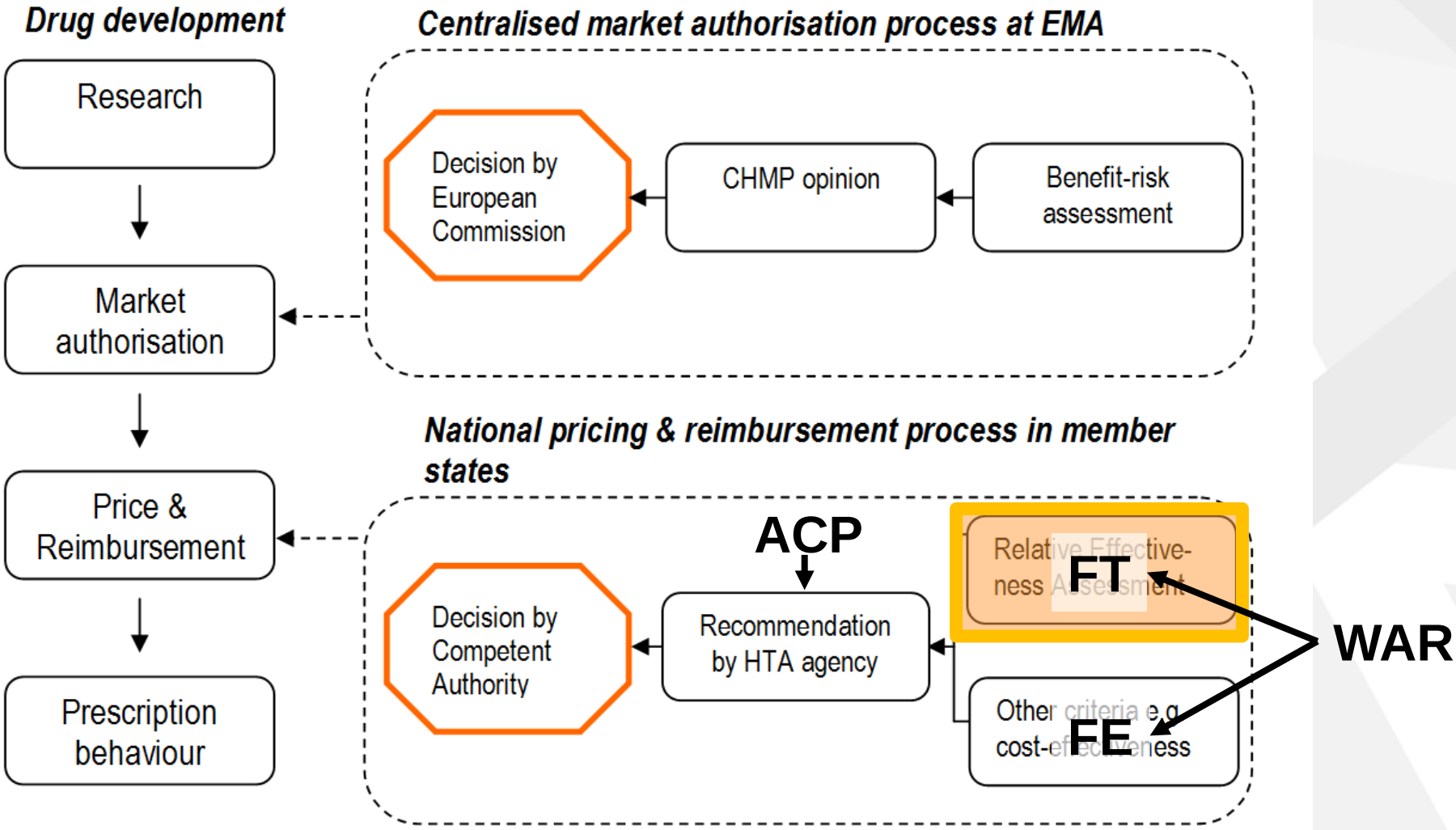
Patients become more ‘European’

Decrease duplication on HTA assessments

Increase consistency between different national HTA assessments

–Variety in type of assessments seems to be common: does this lead to different assessment results?

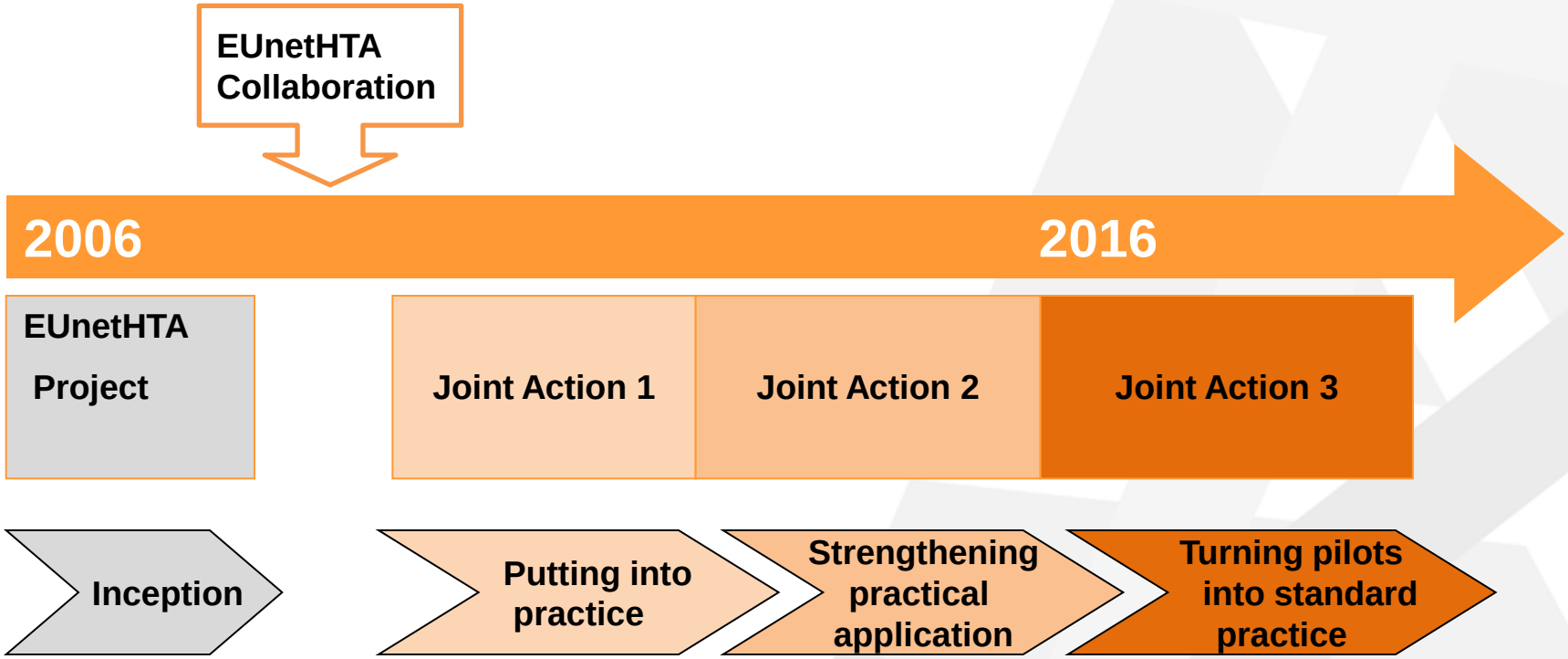
Market Access to Medicines in Europe



Benefits of HTA collaboration in Europe for all stakeholders

- **Timeliness**
  - General earlier access if added value (and value for money) is proven
    - In particular earlier introductions in second-tier countries?
- **Consistency (and predictability)**
  - May also indirect influence decisions and support price negotiations
- **Efficiency**
  - Efficient collaboration and reduce duplications
    - In particular for smaller companies with no or limited national affiliates
- **Quality**
  - Guidelines and core model

EUnetHTA (voluntary collaboration)
Historical timeline

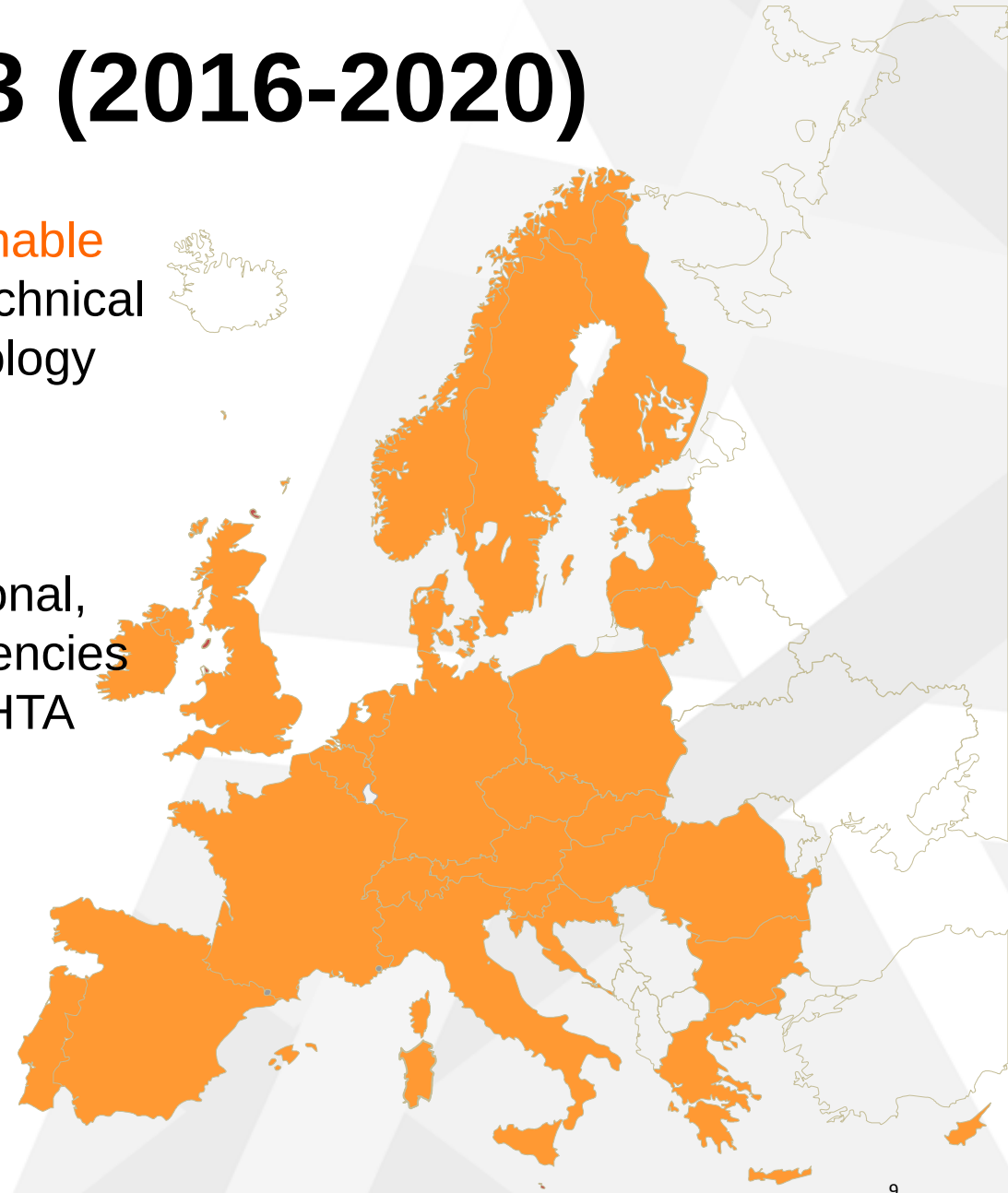


EUnetHTA JA3 (2016-2020)

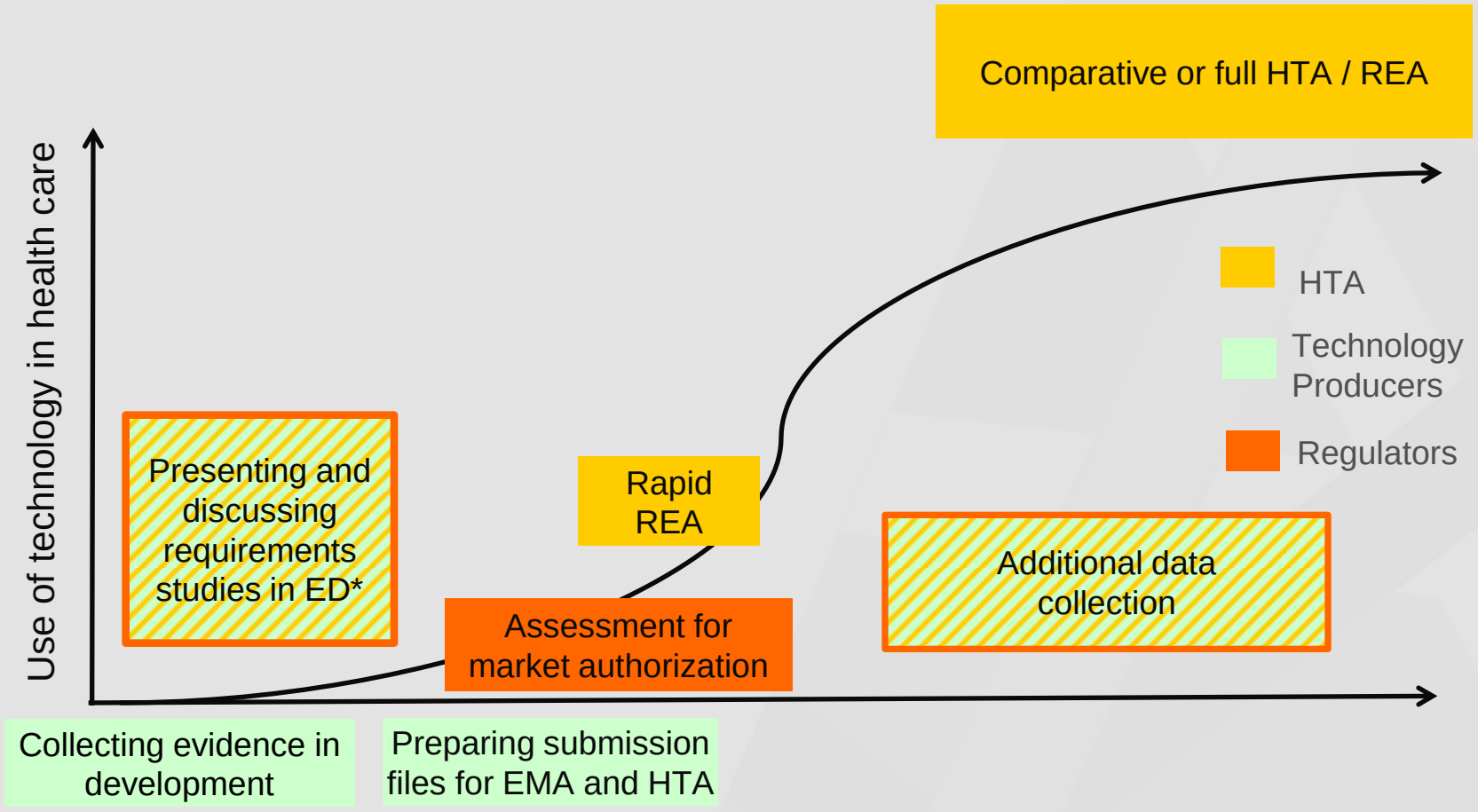
Aims to contribute to a sustainable model for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe

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

Project Coordinator:
Dutch National Health Care Institute (ZIN)

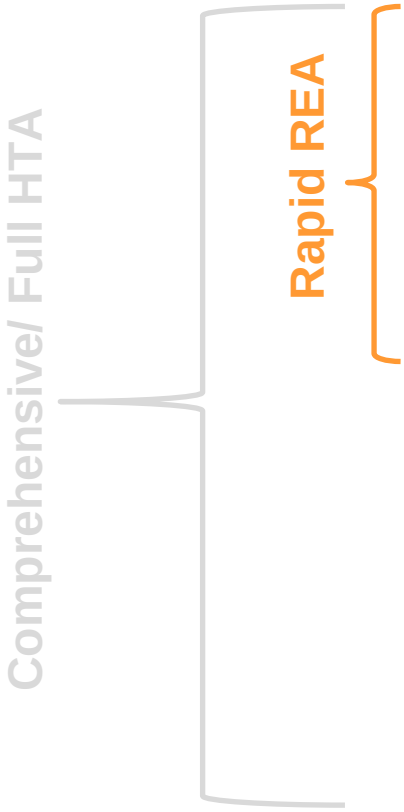


HTA in the life cycle of technologies

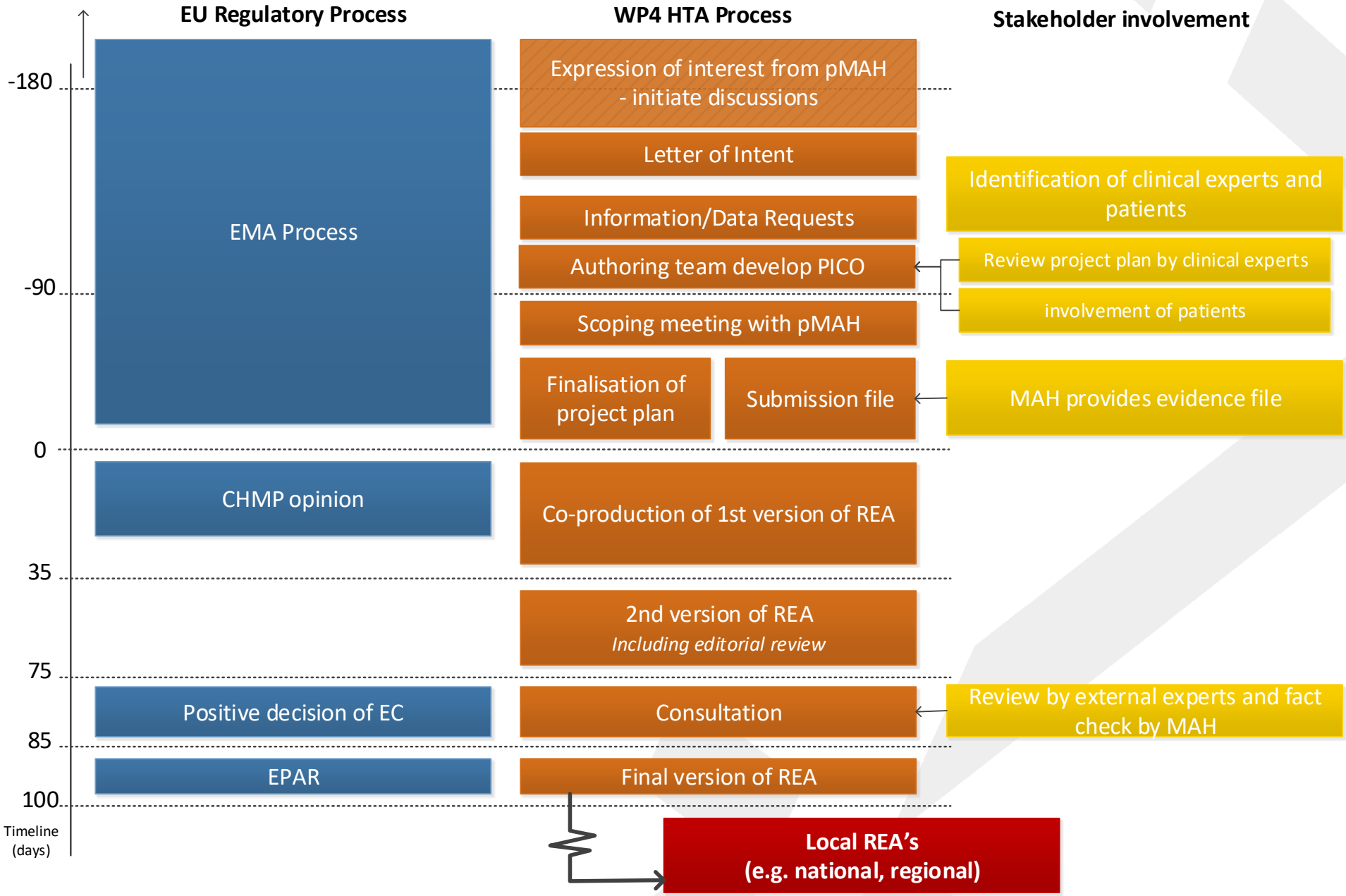


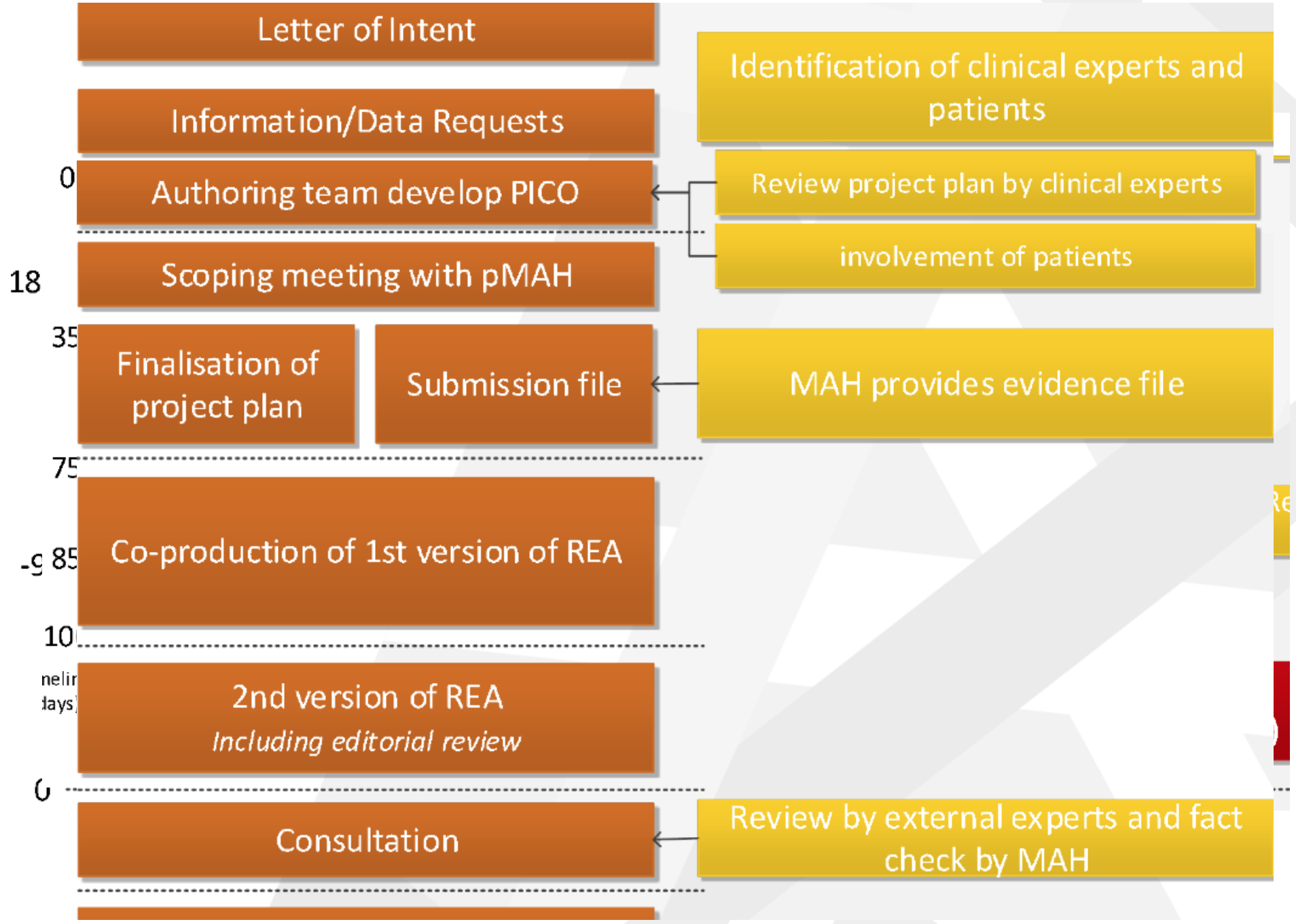
Early dialogue

EUnetHTA HTA Core Model®



HTA Core Model DOMAINS
1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects


EU Regulatory Process
WP4 HTA Process
Stakeholder involvement
-180
-90
0
35
75
85
100
Timeline (days)
EMA Process
CHMP opinion
Positive decision of EC
EPAR
Expression of interest from pMAH - initiate discussions
Letter of Intent
Information/Data Requests
Authoring team develop PICO
Scoping meeting with pMAH
Finalisation of project plan
Submission file
Co-production of 1st version of REA
2nd version of REA
Including editorial review
Consultation
Final version of REA
Identification of clinical experts and patients
Review project plan by clinical experts
involvement of patients
MAH provides evidence file
Review by external experts and fact check by MAH
Local REA's (e.g. national, regional)


Letter of Intent
Identification of clinical experts and patients
Information/Data Requests
0
Authoring team develop PICO
Review project plan by clinical experts
involvement of patients
18
Scoping meeting with pMAH
35
Finalisation of project plan
Submission file
MAH provides evidence file
75
Co-production of 1st version of REA
-9
85
10
2nd version of REA
Including editorial review
0
Consultation
Review by external experts and fact check by MAH

Published joint Rapid REA (JA3)- Pharma

Project ID	Title *(Marketing authorization holder)*	Authoring team	Status
PTJA01	Midostaurin for the indication of Acute Myeloid Leukaemia *(Novartis)*	FIMEA, NOMA TLV, ZIN, HAS, NICE, AEMPS, IQWiG (information retrieval), *Observer:* SUKL, SU, EOPPY, SESCS	**Published Nov. 9**
PTJA02	Regorafenib (Stivarga©) indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib *(Bayer)*	HAS, INFARMED AAZ, SNHTA, FIMEA, LBI, NIPN, AETSA *Observer:* EOF, EKAPTY	**Published Oct. 25**
PTJA03	Alecensa as monotherapy is indicated for the first- line treatment of adult patients with ALK+ advanced NSCLC *(Roche)*	TLV, HVB, AAZ NICE, Regione Veneto, Uniba, AETSA, NIPN *Observer:* MoH Malta	**Published Jan. 24**

Example of implementation of earlier joint rapid REA (JA2 2015)

Intervention = Ramucirumab (Cyramza®)

- EUnetHTA report* was used for Dutch assessment (EUnetHTA report + Dutch summary)
- Accepted by our technical assessment committee (WAR)
- Significant decrease in time needed to prepare first draft (5 days vs 25 days normally)

*http://www.eunethta.eu/joint-assessment-on-ramucirumab-cyramza-in-combination-with-paclitaxel-as-second-line-treatment-for-adult-patients-with-advanced-gastric-or-gastro-oesophageal-junction-adenocarcinoma/

Use of EUnetHTA template for GVS assessment

Zorginstituut Nederland

GVS-rapport 18/02
Cladribine tabletten (Mavenclad®)

Datum 9 januari 2018
Status Definitief

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

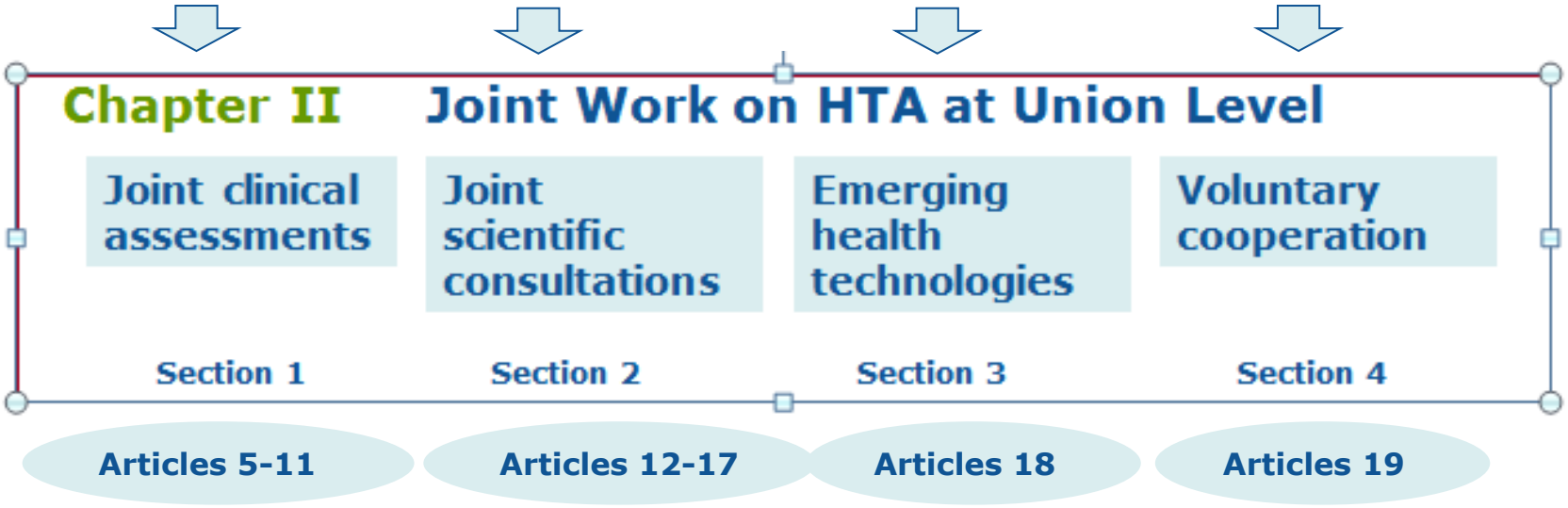
on health technology assessment and amending Directive 2011/24/EU

- The Regulation establishes:
  - **a support framework and procedures for cooperation on health technology assessment at Union level;**
  - **common rules for the clinical assessment of health technologies.**
- The Regulation **shall not affect** the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.

Areas of joint work

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint REA | **Data generation** | **Horizon scanning** | **Collaborative assessments Non-clinical assessments…**



FUTURE AFTER 2020

LEGAL PROPOSAL

European Commission

Articles 3-4

HTA Coordination Group (CG)

Joint work carried out by MS experts

CG Sub-groups

Joint clinical assessments (JCA)
⇓
JCA reports
MP MD

Joint scientific consultations (JSC)
⇓
JSC reports
MP MD

Identification of emerging health technologies
⇓
Input for annual work programme
MP MD

Voluntary Cooperation
⇓
Collaborative assessments / non-clinical domains

Stake-holder Network

Preparation of the annual work programme/annual reports, updates of the common requirements and guidance documents

EC Secretariat

Administrative support
(e.g. meetings, planning)

Scientific/technical support
(e.g. scientific secretariat to rapporteurs, quality management)

IT support
(submission system, databases, intranet)

Support and monitor uptake
(notification, adaptation common tools/brokering).

Timeline

- Member States **may delay their participation** in the system of JCA and JSC until **3 years after the date of application**
- **Prioritization** of health technologies subject to JCA, JSC

Conclusions

- NL, in particular ZIN, is playing a leading role in implementing the EUnetHTA methods in national practice
  - Focus on voluntary collaboration for clinical assessments (FT)
    - Clear interaction with the regulatory process (timeliness, efficiency)
  - By using the joint EUnetHTA REA reports in the national practice (top-down)
  - By using the EUnetHTA REA template for national assessments (bottom-up)
- Legal proposal EC on HTA collaboration shows permanent system for HTA after 2020
  - Experiences EUnetHTA will provide the framework for the permanent system after 2020
    - JCA will be based on the EUnetHTA methods for REA
- The discussion with Council and EP will mostly focus on to which extent this future process will be voluntary/mandatory

Thank you

Any Questions?