EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory HTA parallel Scientific Advice throughout the life-cycle of the product

Industry stakeholder platform on research and development support

Presented by Jane Moseley on 25 April 2017
Senior Scientific Officer, Scientific Advice

An agency of the European Union

Parallel EMA/HTA scientific advice (early dialogue)

Starting point: Regulators and HTAs

- answer different questions
- have different requirements in terms of evidence

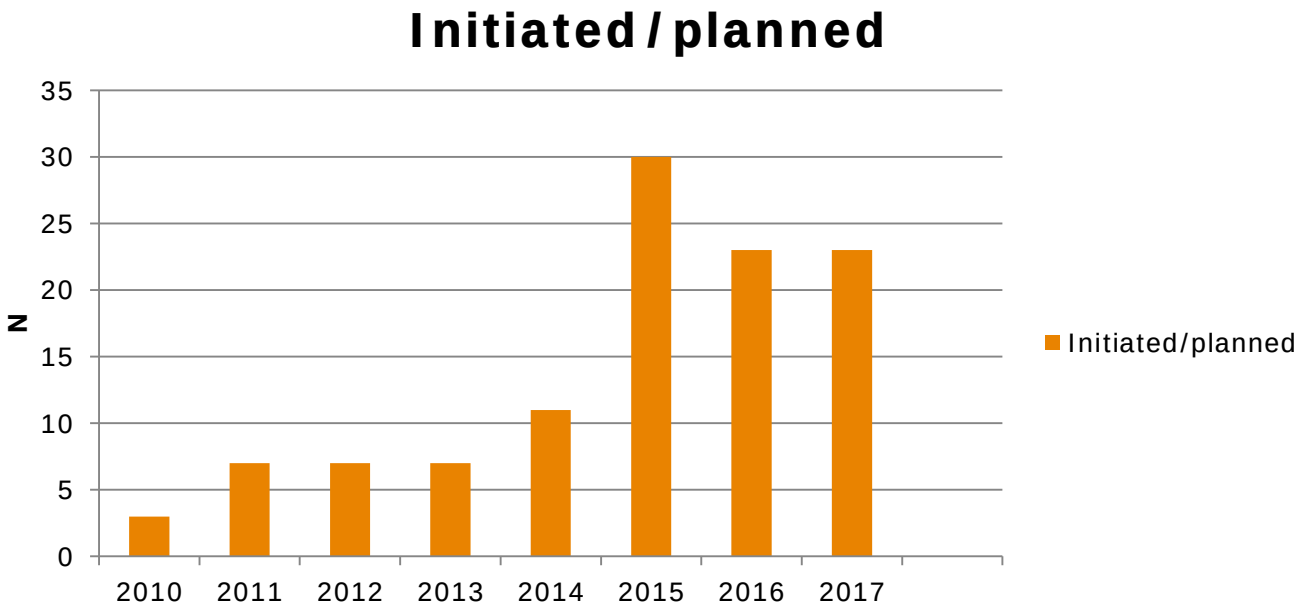
Aim: decision makers come together early

- to discuss the planned development including
- Populations/Comparators/design of trial/endpoints

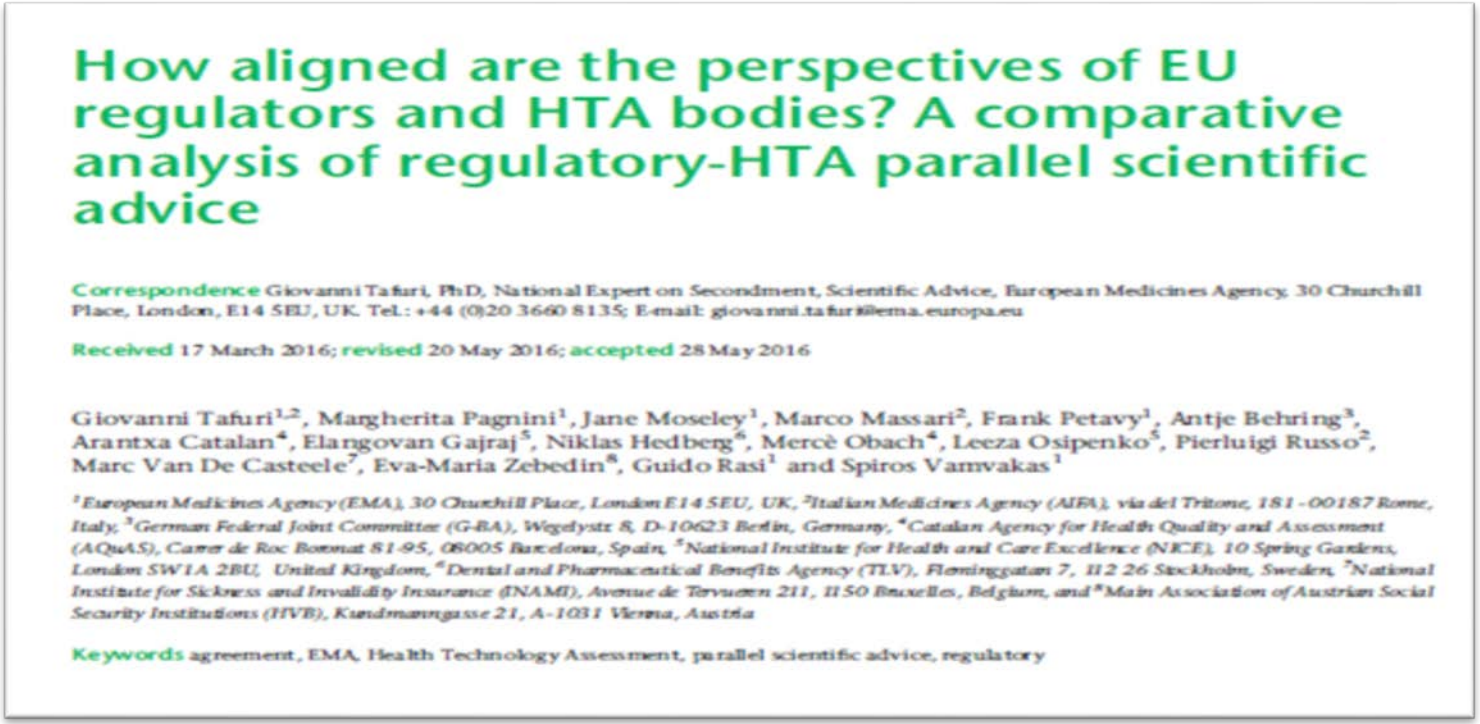
Expectation: Optimised development plan ➔ Improve access for patients

Across the life cycle; early, late, and qualification (non product related)

EMA HTA Parallel SA: procedures as of April 2017



- Joint publication
- 2nd phase of compliance assessment ongoing



How aligned are the perspectives of EU regulators and HTA bodies? A comparative analysis of regulatory-HTA parallel scientific advice

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Reasons why companies may be hesitant to come for parallel advice?

- "time taken for advice especially in accelerated development program"; procedure shortened
- "hesitancy to take up something when still 'pilot' or consequences are not clear"; now >100 procedures registered
- "Company is US focused, difficult to convince re significance of parallel advice to US colleagues": communication needed
- "Anxiety about blurred remits" - no evidence of 'contamination'
- other possible HTA/company related issues?

Latest developments on process improvement

Parallel advice

- **EUnetHTA** Observers routinely invited to Parallel advice
- HTA recruitment- discussions on coordination
- Rotating HTA scientific coordinators (HTA co-Chair, compiling single HTA list of issues)

HTA-only EDs

- EMA will be observer

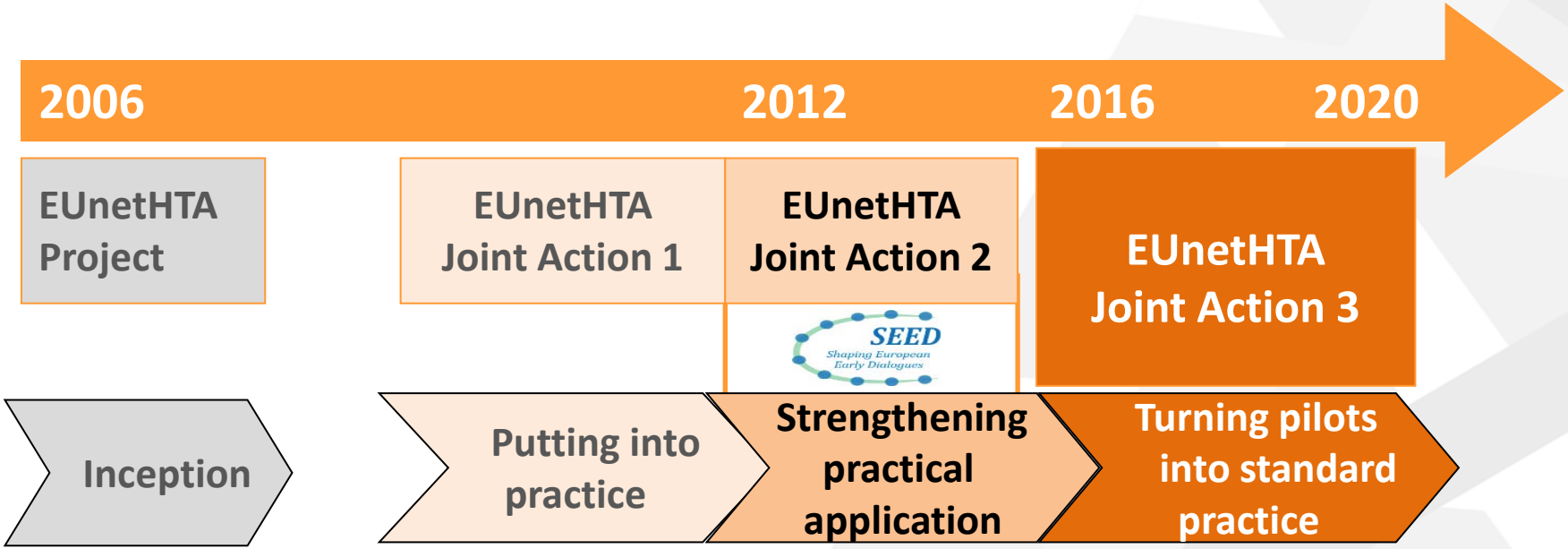
EMA EUnetHTA multi-stakeholder parallel advice

- morphing to one final platform, ongoing discussions EC included

EUnetHTA activities on Early Dialogues / Scientific advice (ED/SA)

François Meyer MD
On behalf of EUnetHTA Work Package 5
Lead Partner : HAS, France
Co-lead partner: G-BA, Germany
London, April 25th 2017

European Cooperation on HTA

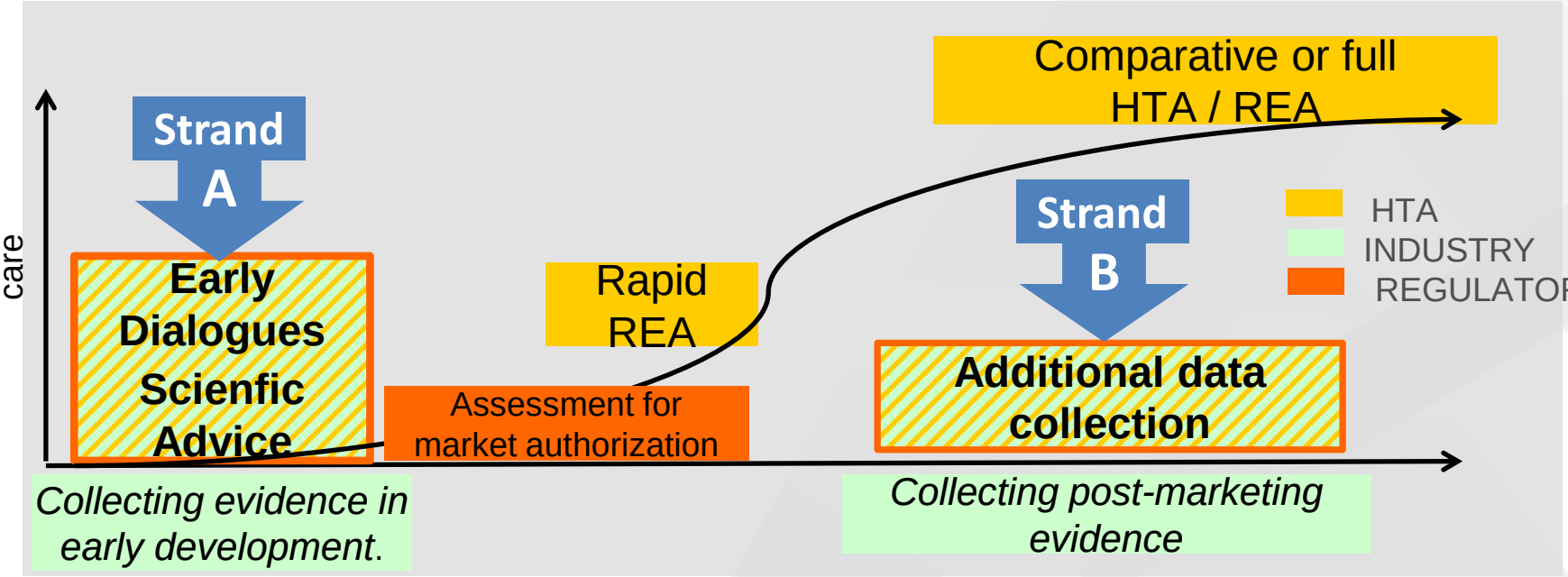


Final objective of JA3

Set up practical conditions for a permanent (post-2020) collaboration

WP5: Life cycle approach to improve Evidence Generation

Lead: HAS
Co-lead: G-BA



Global coordination: ZIN

Improvement of EDs: Set up of a Working Party

EUnetHTA Early Dialogue Working Party (EDWP):

- Gathers HTA bodies with important experience in EDs AND important commitment to participate in EUnetHTA EDs
- Current composition:
  - Full seat for: HAS, G-BA, NICE, AIFA
  - NIPN (Hungary) full seat, connection with other Eastern Europe agencies
  - Shared seat between ZIN (NL) and RIZIV INAMI (BE)
  - Possibility of having an alternate institution tested in IT (RER, HTA body for Emilia Romagna, will be alternate to AIFA)

Additional HTA bodies will participate (rotating basis)

- Total number of HTA bodies in WP5 Strand A : 28 partners (16 with experience in Early Dialogues)

Financial aspects

EUnetHTA budget limited:

- 5 EDs scheduled for Year 1, 10 for Year 2
- Necessary to:
  - Establish prioritization criteria for the first two years
  - Put in place a fee for service system to ensure sustainability

Prioritisation criteria

- To be discussed by EDWP (meeting in Paris on April 28)

Funding

- Implementation of a fee for service system currently being evaluated
- In the meantime, possibility of conducting Early Dialogues with HTA bodies financed by EUnetHTA and other receiving fees from companies is being under study (Approval from European Commission needed)

WP5 Strand A activities

Activity	2016	2017 Q1	2017 Q2/Q3
Preparatory activities	Done		
EDs pharmaceuticals multi HTA		Launch January 2017	
EDs for Medical Devices		Dialogue with Medtech industry Launch Q2 2017	
Financing	Study on possible scenarios for a future fee-for-service financing (Ongoing) Transition phase : Possible hybrid financing?		
EDs pharmaceuticals Parallel EDs with EMA	Preparatory work (see next slide)		Launch

Principle for Parallel Dialogues/Advice

1) **Central recruitment** of HTA bodies by **EUnetHTA** for all parallel ED/SA
2) EUnetHTA will **ensure coordination** between HTA bodies during the whole process of all parallel ED/SA
3) EUnetHTA will engage as much as possible the **EDWP** in the parallel EDs/SAs