

The first experience with the newly launched Parallel Consultations

Chantal Guilhaume

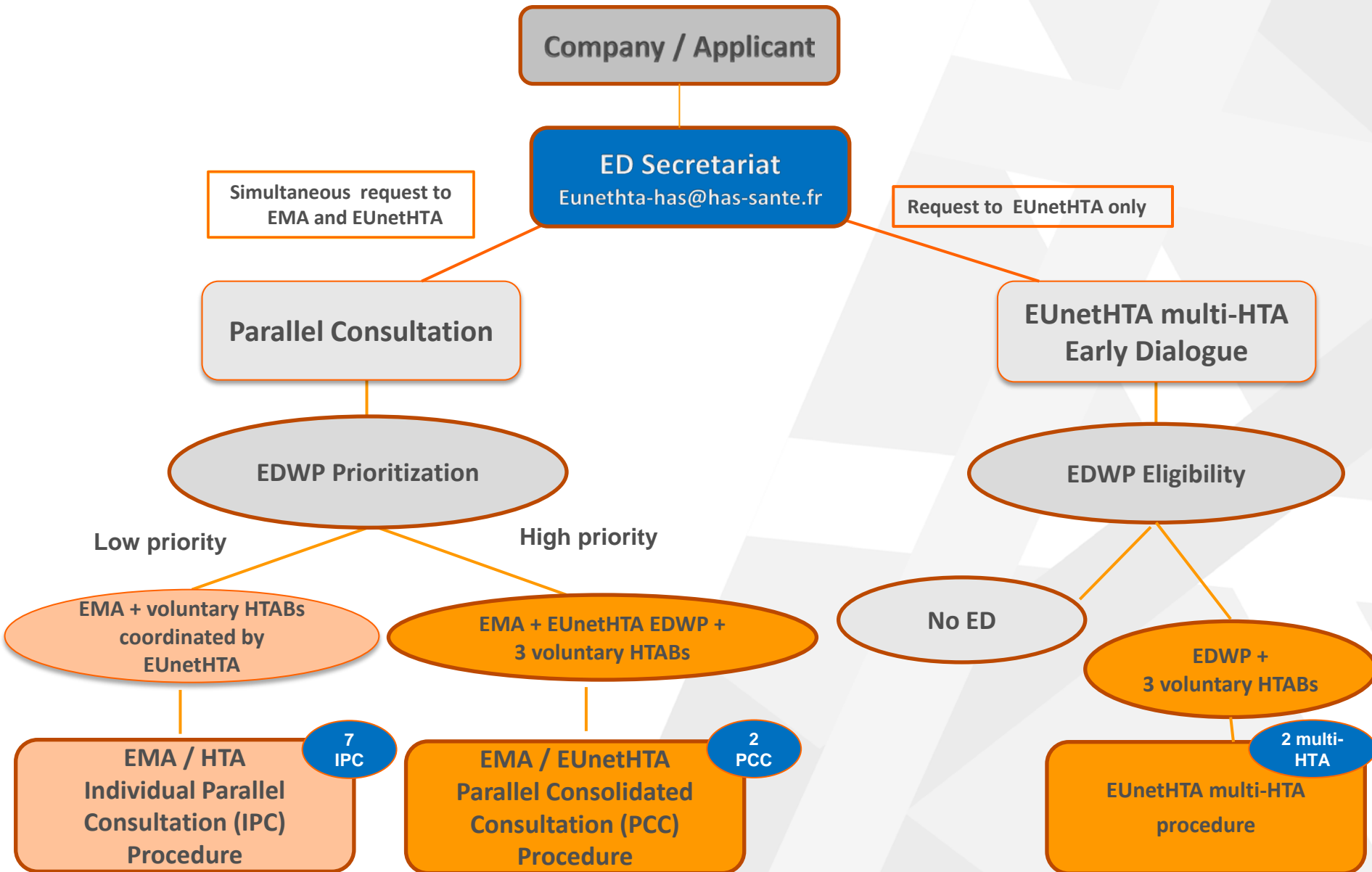
On behalf of EUnetHTA Work Package 5A

Lead Partner : HAS, France

Co-lead partner: G-BA, Germany

London, November 13th 2017

One gateway for all procedures involving HTABs



Specificities of EUnetHTA Early Dialogues

- **Prioritization criteria :**
 - Product should aim at bringing added benefit to patients, i.e. by:
 - New mode of action for the indication AND
 - Targeting life-threatening or chronically debilitating disease AND
 - Responding to unmet need (no treatment or only unsatisfactory treatment available)
- **Participation of EDWP members** up to 3 additional HTABs
 - Standing participants: HAS, G-BA, NICE, AIFA/RER, NIPN, ZIN/RIZIV-INAMI
- **Consolidated final recommendation**
- **Cost currently covered by EUnetHTA or by fees**
 - Currently fees required for NICE. Other HTABs may join.
 - Current EUnetHTA budget for ~15 EDs

Greater coordination since July 2017

- **Centralised project management by the EUnetHTA ED Secretariat**
- **Identification of a scientific coordinator at the beginning of the process**
 - For PCC/multi-HTA, scientific coordination/rapporteur roles ensured by HAS and G-BA (alternate every 5 EDs)
 - For IPC, scientific coordinator chosen among HTAB participants
- **Exchange of List of Issues**
 - Exchange between EMA and HTABs on consolidated List of Issue
 - Identification of commonalities on identified issues and EUnetHTA/EMA position
 - Opportunity to discuss distribution of roles EMA/EUnetHTA during F2F meeting

Still room for improvement....

- **Feedback from applicant**
 - Procedure
 - Templates
 - F2F meeting
 - Final recommendations and impact on development plan
 - Applicant's investment
 - Inclusion of stakeholders

- **Further collaboration with EMA on HCP and patients contribution**



Strengthening the prospective discussions on post-licensing evidence generation

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On behalf of EUnetHTA Work Package 5B

Lead Partner : HAS, France

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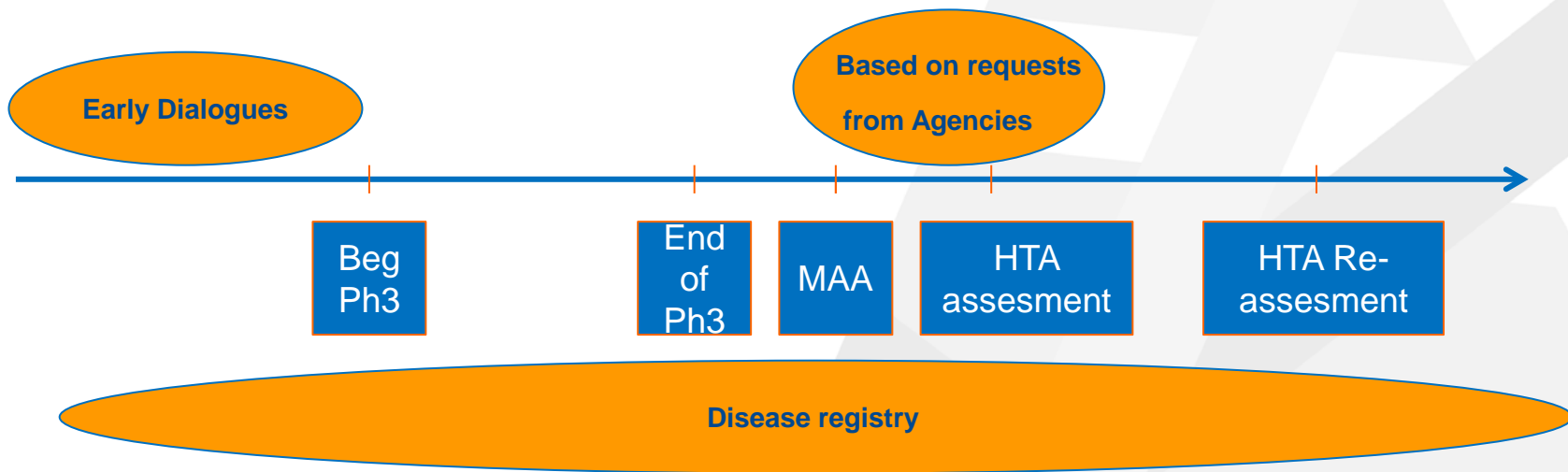
A Work Package dedicated within EUnetHTA to PLEG

WP5 B - Lead Partner: HAS

- **Objective:**

Define process of generating post-launch evidence from clinical practice over the cycle of health technology and using it for re-assessment and reimbursement decisions

- **When to discuss PLEG**



EUnetHTA tools for PLEGs

1 2 3

Documents available
www.w.eunetha.eu

Need to collect more data in the post-marketing phase?

1 **EUnetHTA**
Criteria to select and prioritize health technologies for additional evidence generation

Definition of the research question

2
eunetha
Position paper on how to best formulate research recommendations

Choice of data sources and methodology

3
eunetha
Position Paper on how to decide on the appropriate study design
for primary research arising from HTA reports

Quality of registries

Standardised tool to assess registry quality



PLEG pilots – EUnetHTA actions

- **EUnetHTA will NOT organise and/or finance the data collection system (registry or other)**
- **Requests for PLEG are made at national level (part of the national decision process). EUnetHTA has no remit to provide a binding recommendation on PLEG**
- **EUnetHTA can support national decision on PLEG by**
 - Proposing a common research question or minimum data set
 - Giving advice on methodology (if registry used, assessing its quality for HTA purposes)
- **Aim: reduce differences between national requests regarding non context-specific information**
 - on disease specific registries: one done, one starting, with EMA
 - on specific drugs: candidates to be chosen before end 2017

