AMS
Advanced Medical Services

EMA-EUnetHTA Parallel Consultation

Current State, AMS Expertise and Services

One Data Package to Meet Different Requirements

AMS
Advanced Medical Services

Study Data

Marketing Authorisation

- Benefit-Risk-Ratio
- Safety
- Efficacy
- Quality

Health Technology Assessment

- Therapeutic (added) value /cost-effectiveness
- Relative Efficacy
- Relative Effectiveness

Payers

- Value
- Affordability

Requirements for HTA may differ across Member States based on national and regional legislation

Two Different Questions

Marketing authorisation (MA)/ Clinical studies	HTA/ Evidence based medicine (EbM)
Does it work?	*Is it better?*
• **Efficacy**: „Yes or No“-decision based on **prospective** studies	• Relative **Effectiveness**: **Retrospective** analysis of existing study data
• Proof of efficacy based on a formal confirmatory test	• Description of existing evidence: Effect size and reliability of the recommendation
• Focus on primary endpoint, secondary endpoints exploratory/supportive	• Patient relevance is key: No differentiation between primary and secondary endpoints
→ *Approval based on a positive benefit-risk balance*	→ *Added value based on clinical evidence*

AMS – Diversity

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Proof of efficacy
Prospective analysis

- Clinical studies
- Biostatistics & Data Management
- Pharmacovigilance
- Quality assurance
- Regulatory Affairs

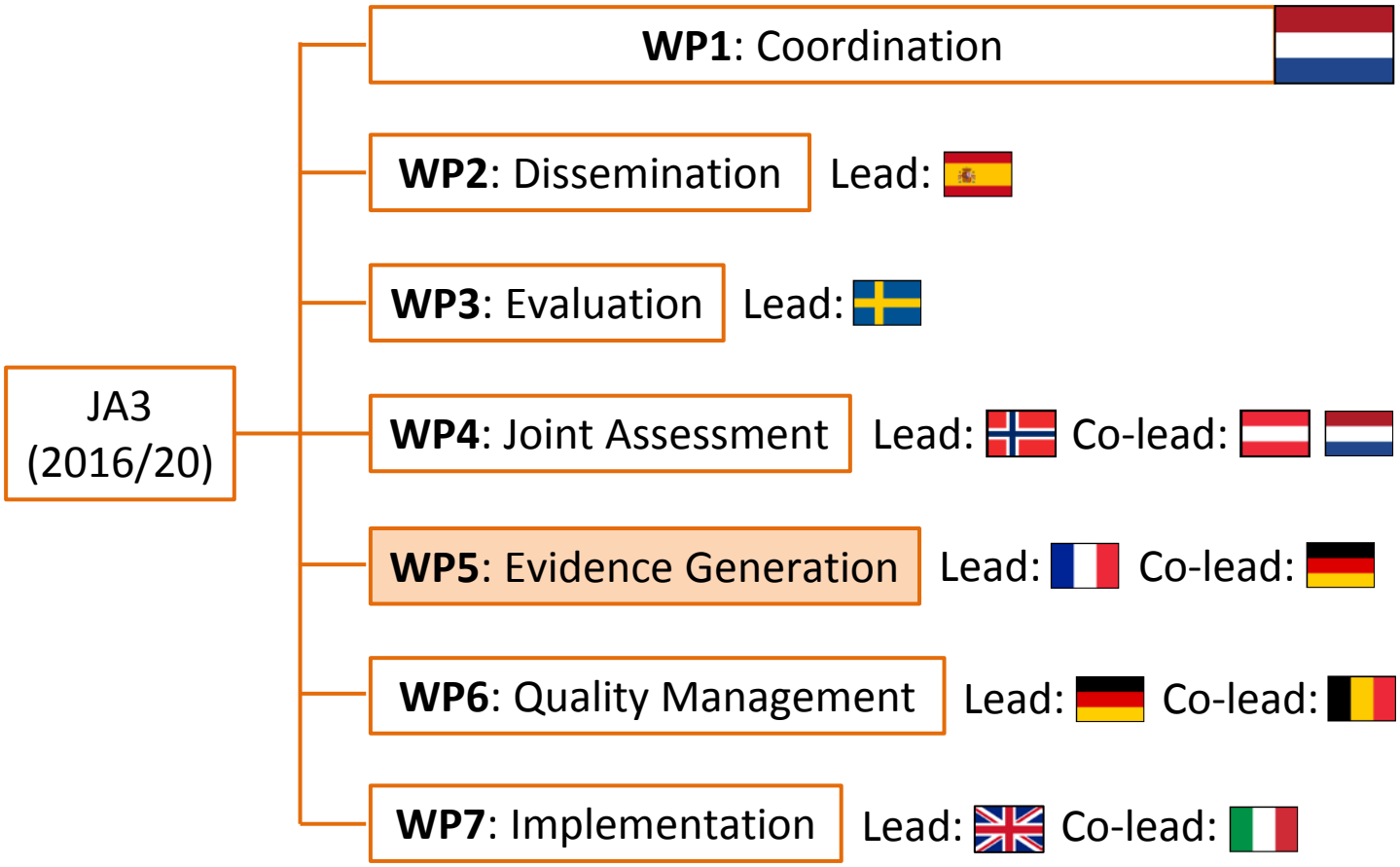
Clinical Research:
Scientific basis for marketing authorisation

- European joint and national benefit assessments
- Systematic searches of literature and study registries
- Biostatistics & health economic analyses
- Pricing, reimbursement, and negotiations

Parallel Consultation & HTA:
Scientific basis for decision-making in healthcare

Relative effectiveness
Retrospective analysis

EUnetHTA JA3 – Activities



JA3, EUnetHTA Joint Action 3; **WP1-7**, Work Packages 1-7

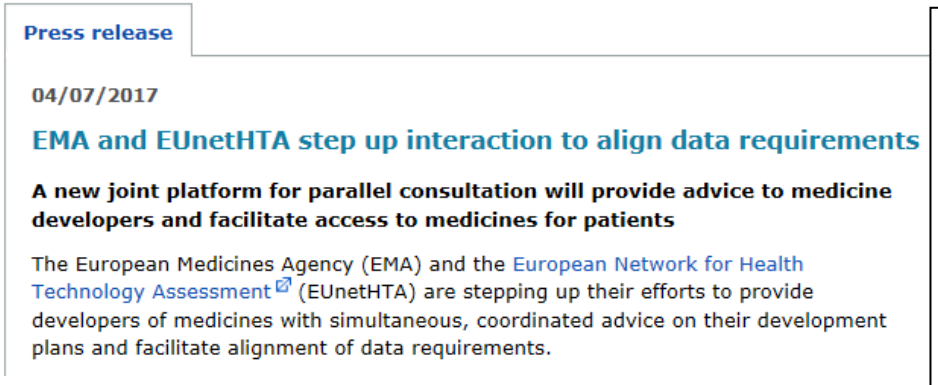
EMA-EUnetHTA Parallel Consultation

AMS Advanced Medical Services

Enhanced collaboration between EMA and EUnetHTA:
A single gateway for requests for parallel discussions (since 07/2017)

- Simultaneous advice from EMA ***AND*** HTA bodies (HTABs)
- Initial Evidence Generation: Before start of pivotal clinical trials
- For Post Licensing Evidence Generation (PLEG)

  Objective: To help generate optimal and robust evidence in an efficient development plan that satisfies the needs of both regulators ***AND*** HTABs



Press release

04/07/2017

EMA and EUnetHTA step up interaction to align data requirements

A new joint platform for parallel consultation will provide advice to medicine developers and facilitate access to medicines for patients

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) are stepping up their efforts to provide developers of medicines with simultaneous, coordinated advice on their development plans and facilitate alignment of data requirements.

Press Release: EMA and EUnetHTA step up interaction to align data requirements

4 July 2017

A new joint platform for parallel consultation will provide advice to medicine developers and facilitate access to medicines for patients

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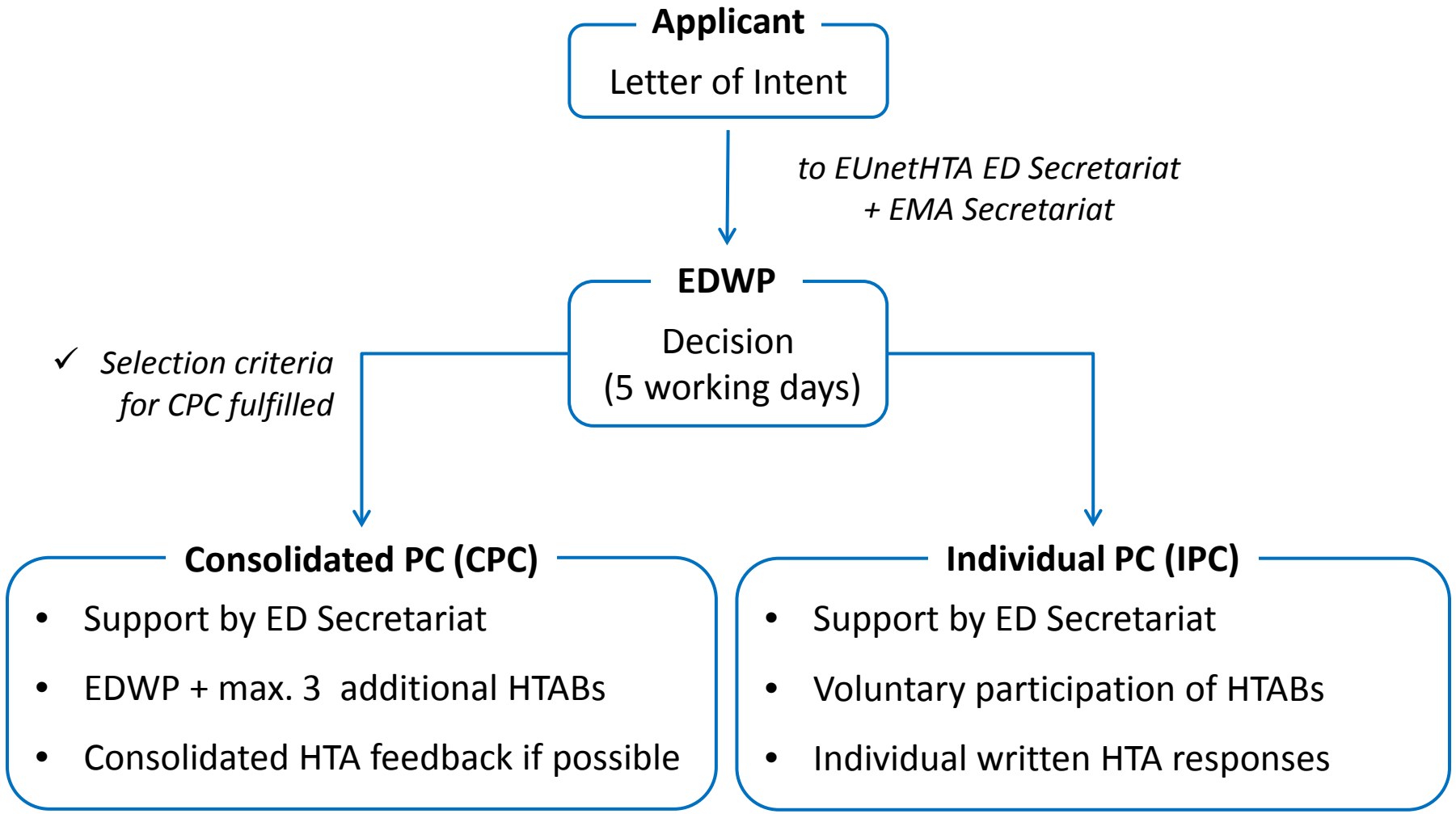
Parallel Consultation – Developments & Improvements

Benefits of the new platform:

- More structured interaction between EMA & HTABs, streamlined logistics
- One point of contact for the applicant
- Improved coordination and greater participation of HTABs (central recruitment by EUnetHTA ED Secretariat)
- Advice at any stage of the product life cycle possible
- EDWP: Stable group of HTABs with significant experience in EDs
- Inclusion of patient representatives on a routine basis

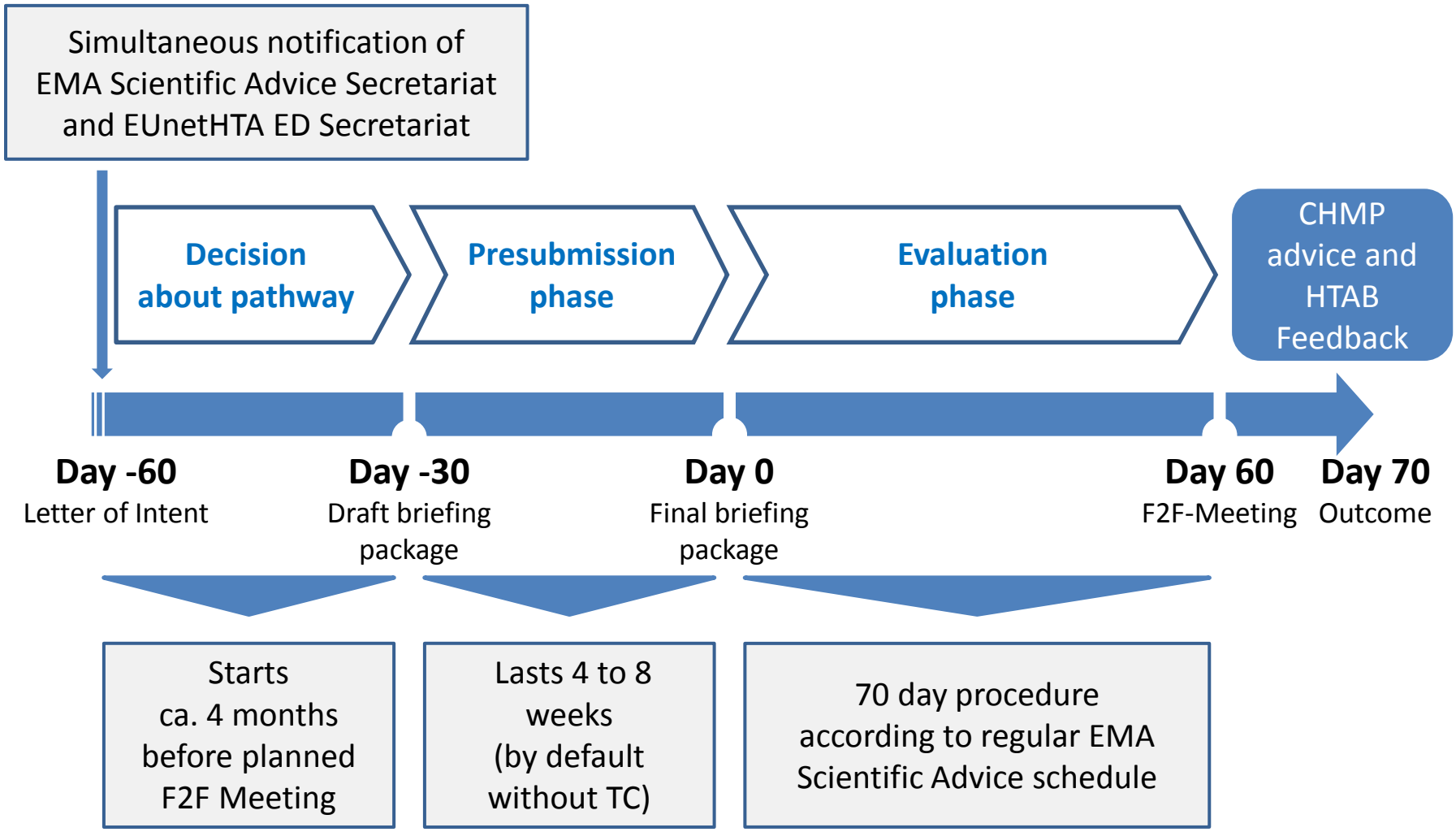
ED, Early Dialogue; **EDWP,** Early Dialogue Working Party

One Procedure – Two Pathways



PC, Parallel Consultation; **CPC,** Consolidated Parallel Consultation; **IPC,** Individual Parallel Consultation

Parallel Consultation – Process



Reference: Guidance for PC: http://www.eunethta.eu/sites/default/files/Guidance%20on%20Parallel%20Consultation.pdf

Parallel EMA/HTAB Advices: Your Benefits

- *Simultaneous feedback from Regulators and HTA Bodies: Align expectation across stakeholders*
- *Understand different data requirements, alignment or divergence*
- *Manage expectations within your company at an early stage*

What can AMS offer?

Interdisciplinary team	Flexibility	Close cooperation
Experts: Medical, medical writing, regulatory, biostatistics and pharmacoeconomics	**Size:** Due to our size very flexible to manage projects on short notice	**Cooperation:** With industry associations, e.g. presentations at VfA, BPI, EUCOPE, EFPIA
Constantly up-to-date	**Important insight**	**Continuous exchange**
Up-to-date: With recent developments regarding EU HTA: In-depth analysis EUnetHTA guidelines, pilot rapid REAs, templates	**Insight:** Requirements and mindset of authorities involved: Numerous SA procedures on national and European level	**Exchange:** With national HTA bodies and EUnetHTA

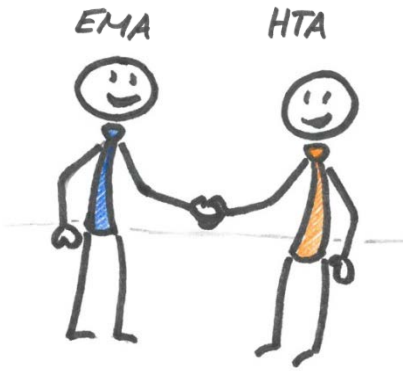
VfA, Verband der forschenden Arzneimittelhersteller (German Association of Researching Pharmaceutical Manufacturers); **BPI,** Bundesverband der pharmazeutischen Industrie (Federal Association of the pharmaceutical industry); **EUCOPE,** European Confederation of Pharmaceutical Entrepreneurs; **EUnetHTA,** European network for Health Technology Assessment; **REA**s, rapid effectiveness assessment; **SA**, Scientific Advice

Future Situation in Europe

Early Dialogue

Marketing Authorisation

Rapid REA



Reimbursement

Common European Standard as foundation for **one** single assessment
→ basis for national uptake and
→ decision-making

Taking diverse health care systems into account

- ✓ **Stronger European voice in global clinical development**
- ✓ **Better business predictability**

Parallel Consultation – Developments & Improvements

Why now?

- Participate in the cooperation at an early stage
- Improve the common understanding of HTA requirements
- Contribute to the development of a learning system
- Be prepared for 2020

Get used to the changing environment,

it is going to change, anyway!

Interested in Learning More?

Medical Science

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