



Council of the European Union
General Secretariat

**Interinstitutional files:
2018/0018(COD)**

Brussels, 09 January 2019

WK 221/2019 INIT

LIMITE

**PHARM
SAN
MI
COMPET
IA
CODEC**

**DOCUMENT PARTIALLY ACCESSIBLE TO
THE PUBLIC (04.08.2022)**

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (HTA)
N° Cion doc.:	5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 + ADD 2 + ADD 3 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Delegations will find enclosed the EU-netHTA presentation given at the Working Party on 8 January. The EUnetHTA-EMA guidance for parallel consultations and a paper on the impact of parallel regulatory-health technology assessment scientific advice on clinical development will follow as addenda.

PUBLIC

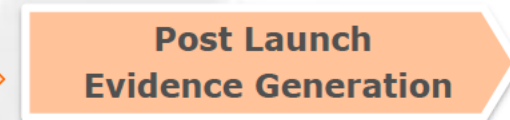
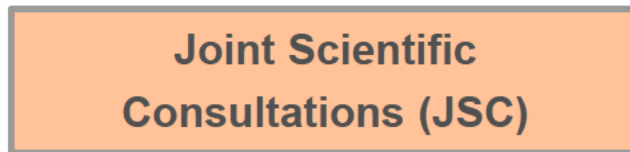
EUnetHTA

Joint Scientific Consultations


 Chief Operations Officer EUnetHTA,
, Scientific Advisor G-BA (WP5A EUnetHTA)

HTA input along drug life cycle

Clinical development



Joint Scientific Consultations (JSC) aim to supply medicine developers with prospective and timely advice on evidence requirements before the start of pivotal clinical trials.

Medicine developers might request JSC by:

- Health Technology Assessment (HTA) bodies ONLY (collaborative approach between European HTA agencies)
- **Health Technology Assessment (HTA) bodies AND regulators (EMA) in parallel**

Study requirements need to be communicated very early in the development process to allow companies to integrate HTA requirements (choice of comparators, relevant outcomes, quality of life, patient groups) in the study design. JSC do not display a pre-assessment of data, but aim to improve the data quality and evidence basis for European HTA assessment procedures.

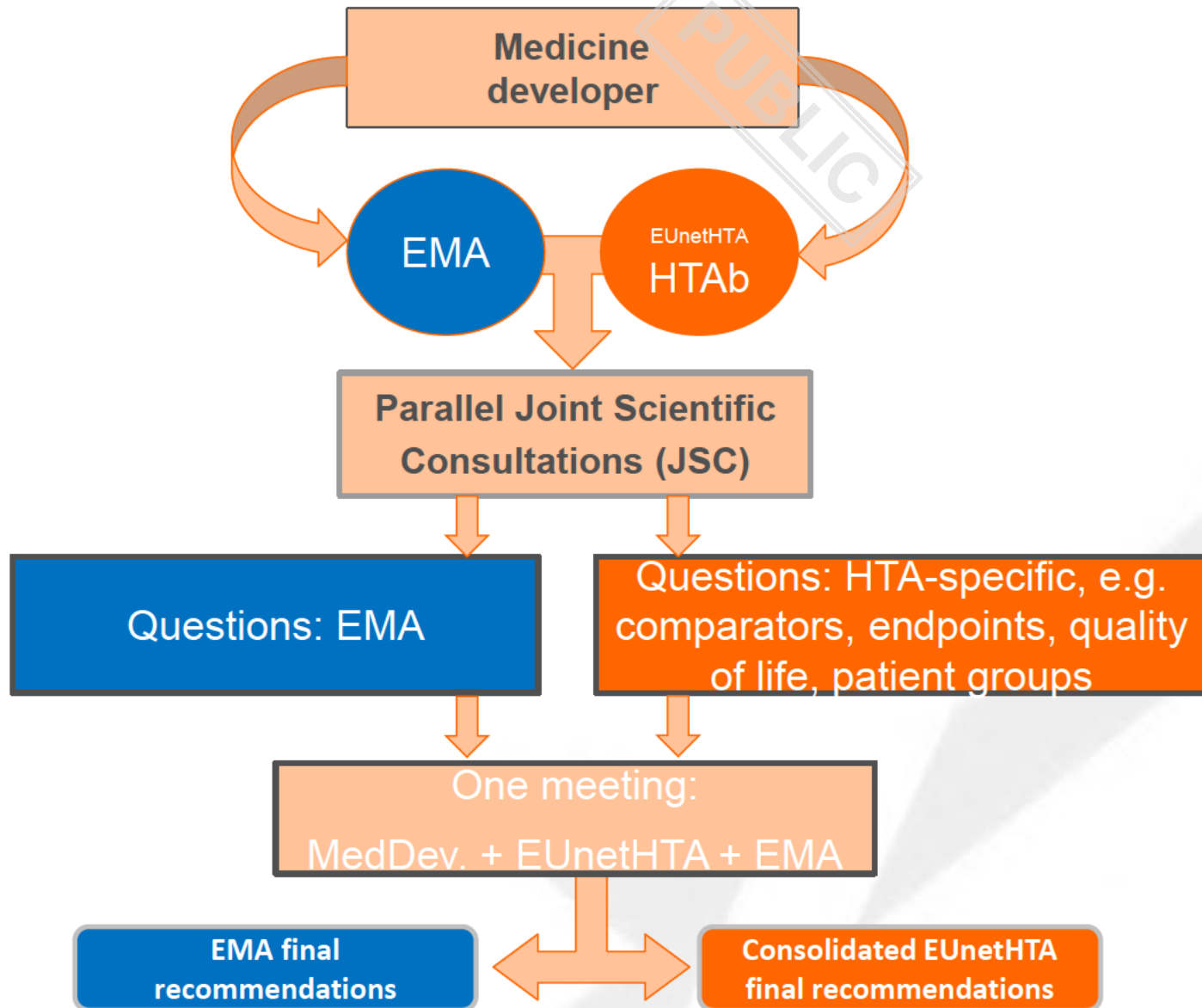
Joint Scientific Consultations of Health Technology Assessment (HTA) bodies AND regulators (EMA) in parallel aim to allow medicine developers to obtain feedback from HTA bodies (HTAb) AND regulators at the same time on their development plans to support decision-making on

- marketing authorisation, AND
- health technology assessment.

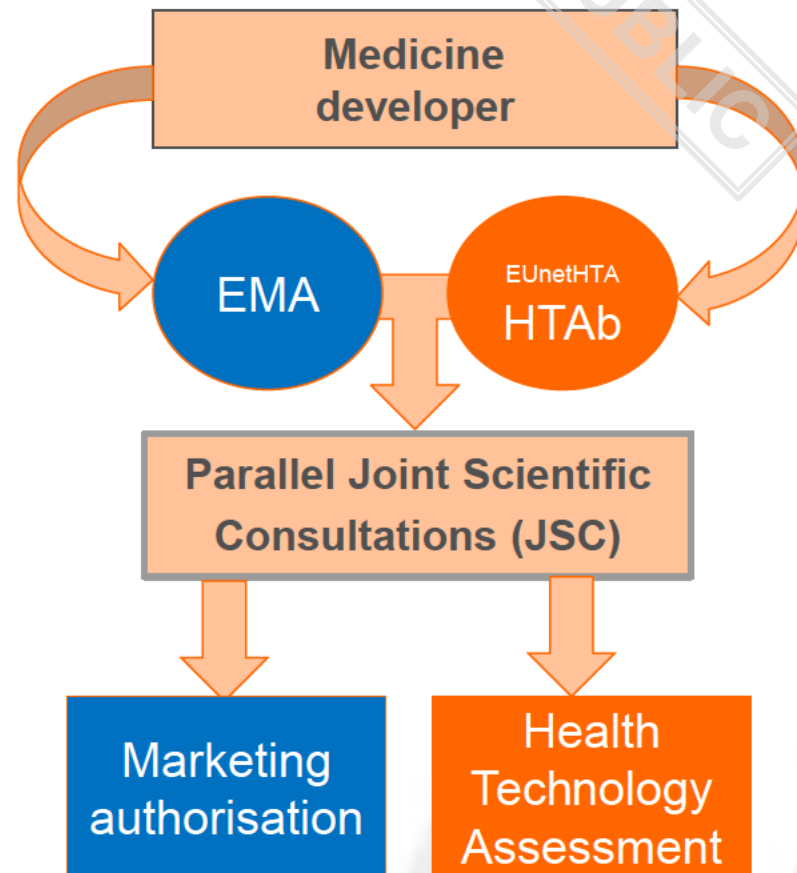
The objective is to help generate optimal and robust evidence that satisfies the needs of both HTA bodies and regulators, respecting the different remits of HTA and regulatory processes.

Based on experience running parallel Scientific advice involving EMA and HTA bodies since 2010, EUnetHTA and EMA offer since 2017 **Parallel Consultations** on evidence generation plans.

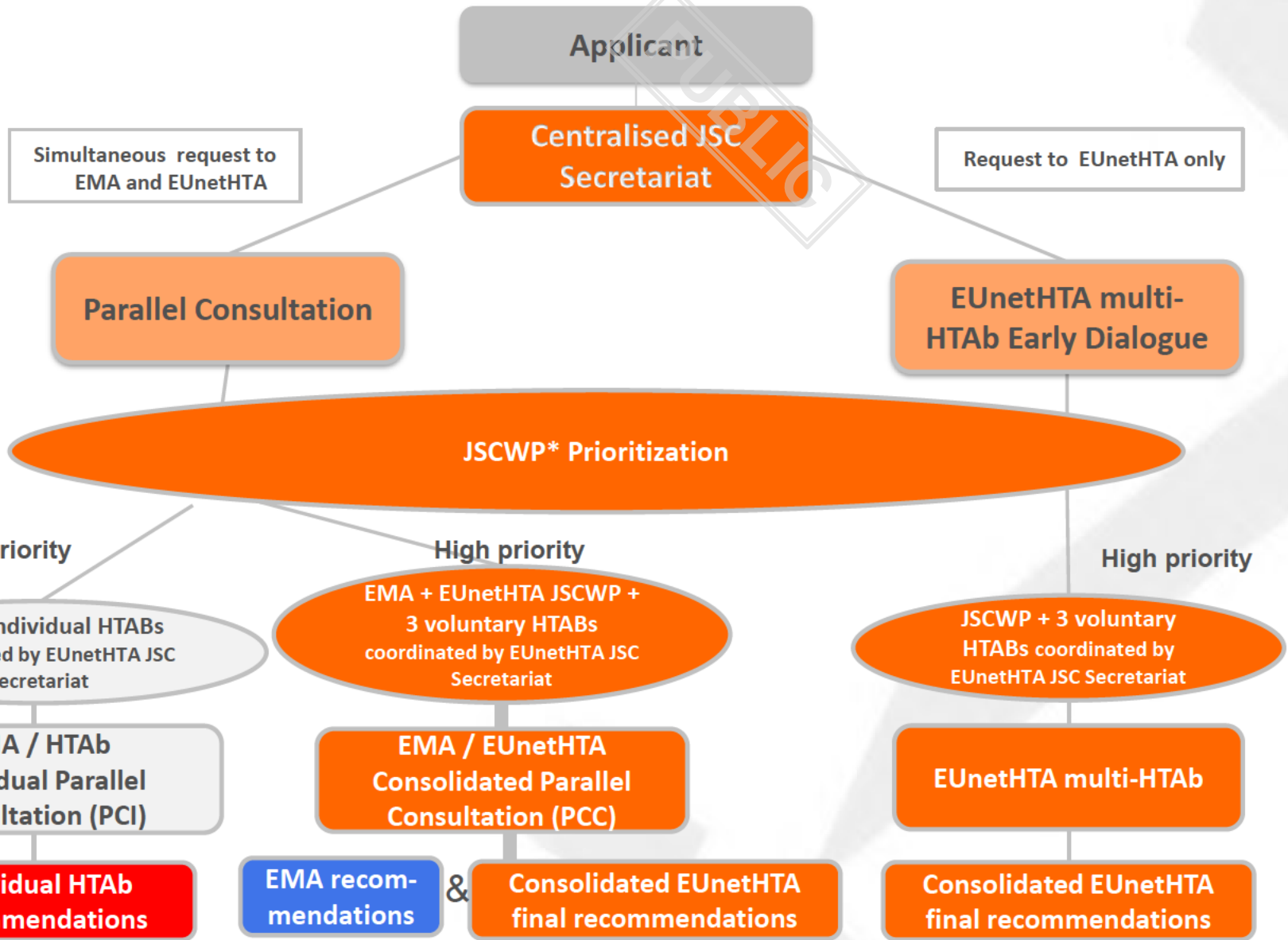
Joint Scientific Consultations (JSC)



Aim of Joint Scientific Consultations (JSC)



One Gateway for all JSC procedures involving HTAbs



Legend: Non-EUnetHTA procedure

EUnetHTA Procedure

*JSCWP: Joint Scientific Consultation Working Party

Current Prioritization Criteria for Parallel Consultations:

The product should aim to bring added benefit to patients i.e. by:

A **new mode of action** for the indication

AND

targeting a **life-threatening** or **chronically debilitating** disease

AND

responding to **unmet need** (no treatment or only unsatisfactory treatment available)

(so far focus on Pharmaceutical products, piloting Medical Device procedures start in 2018/2019)

The JSC Working Party (JSCWP)

= robust and stable group constituted of HTA bodies (HTAb) with substantial experiences in JSC, high level of commitment and sufficient resources => **consistency and predictability**

JSCWP Members: AEMPS(ES), AIFA/RER(I), G-BA(DE), HAS(FR), NICE(UK), NIPN(HU), NOMA(NO)/TLV(SE), RIZIV-INAMI(BE)/ZIN(NL)

Tasks or WP:

- Active participation in JSC general principals and procedural updates
- Apply prioritization criteria to each JSC (transparent manner)
- Participate in all “EUnetHTA” JSCs
- Act as Scientific **Coordinator** and **Rapporteur** for JSCs
- Contribute to expert (patient and clinical) involvement – recruitment and interview
- Comparable to EMA structure (SAWP)



The JSC Secretariat

The JSC Secretariat currently rests with individual HTAbs, specifically it is primarily run by HAS (FR) and is supported by G-BA. The JSC Secretariat functions as one-stop-shop for JSC coordination amongst HTAb. It has a purely administrative function, it holds no decision power over content of the recommendations.

Members: HAS

Tasks of JSC Secretariat:

- Administrative tasks
- Communication with Technology developer
- Communication with EMA
- Communication with JSCWP and other HTABs
- Coordinating patient and expert involvement (Conf. of Interest)
- Replies to general questions
- Preparation of data for meetings



Pharmaceutical JSCs July 2017 through Nov 2018

45 Letters of Intent

Requests	Therapeutic field (from letter of intent)
2	Auto-immune disease/dysfunction
17	Cancer
3	Neurodegenerative disorder
3	Viral disease
17	Other

22 Individual Parallel Consultations

Including 1 vaccine
16 Completed
6 On-going

*2 SME applicants
3 Orphan drugs
0 ATMP*

17 EUnetHTA JSCs (3 Multi-HTA + 14 Consolidated Parallel Consultations (PCC))

6 Cancer
2 Neurodegenerative disorder
1 Viral disease
8 Other

*6 SME applicants
9 Orphan designations
4 ATMP*

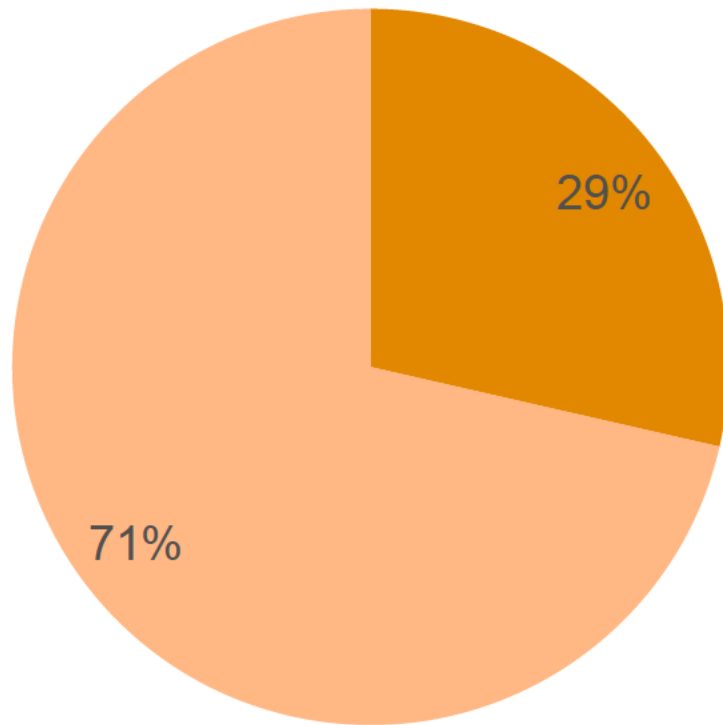
14 Completed (as of Nov 2018)

4 withdrawn (by the Applicant, 1 resubmitted and accepted as PCI)
2 declined (procedure not followed; did not meet eligibility criteria for multi-HTA)



Impact of JCSs on the development plan

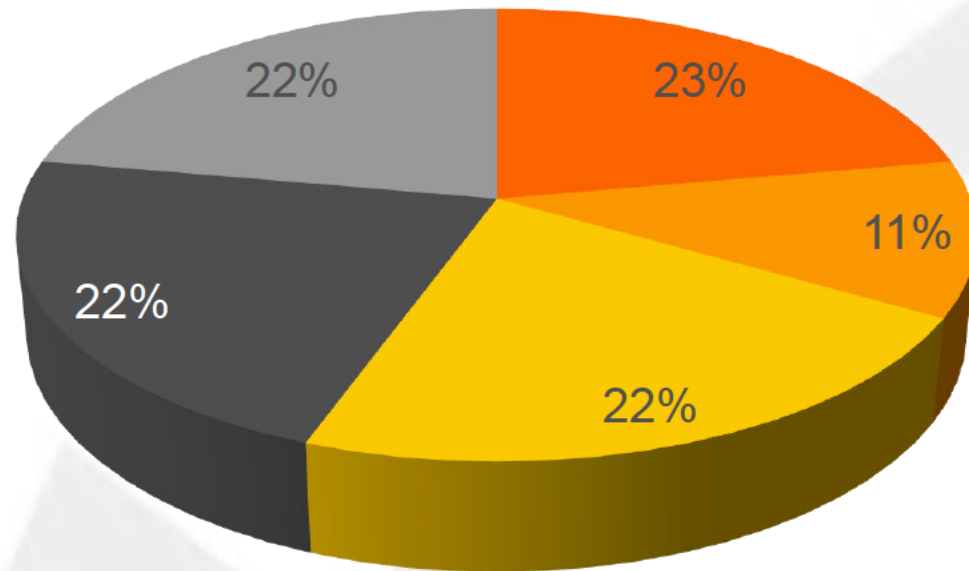
Were changes made to development plan?



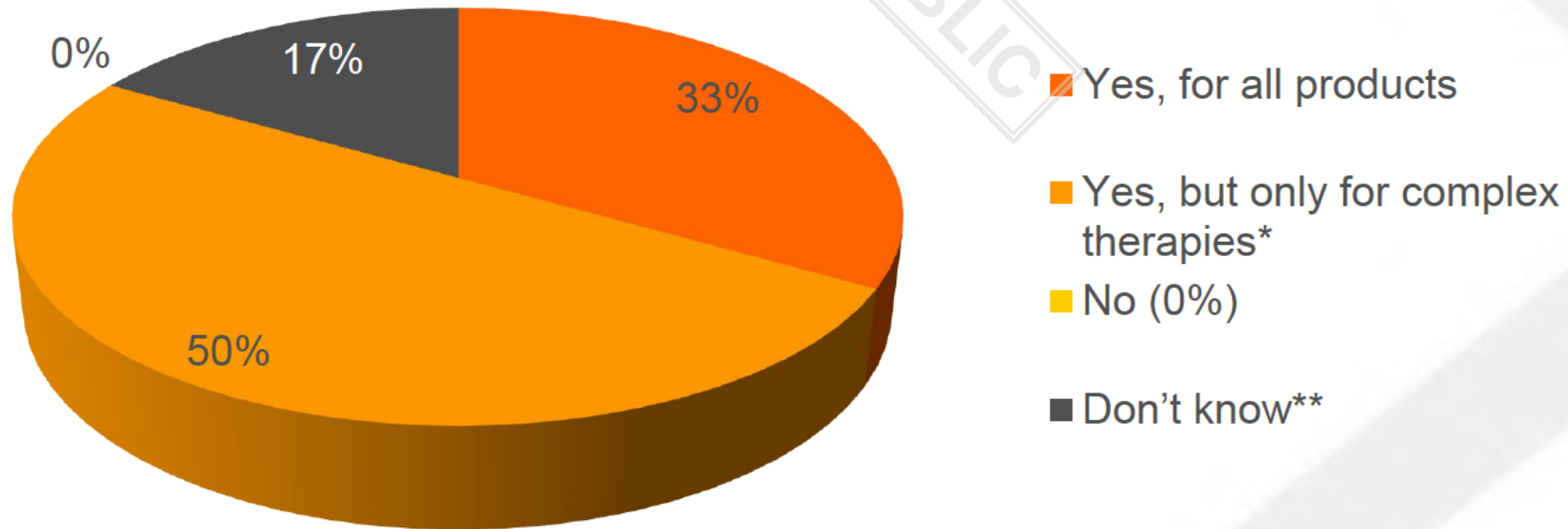
■ No ■ Yes

Where?

- Population
- Endpoints
- Economic model
- Comparator
- Clinical trial design



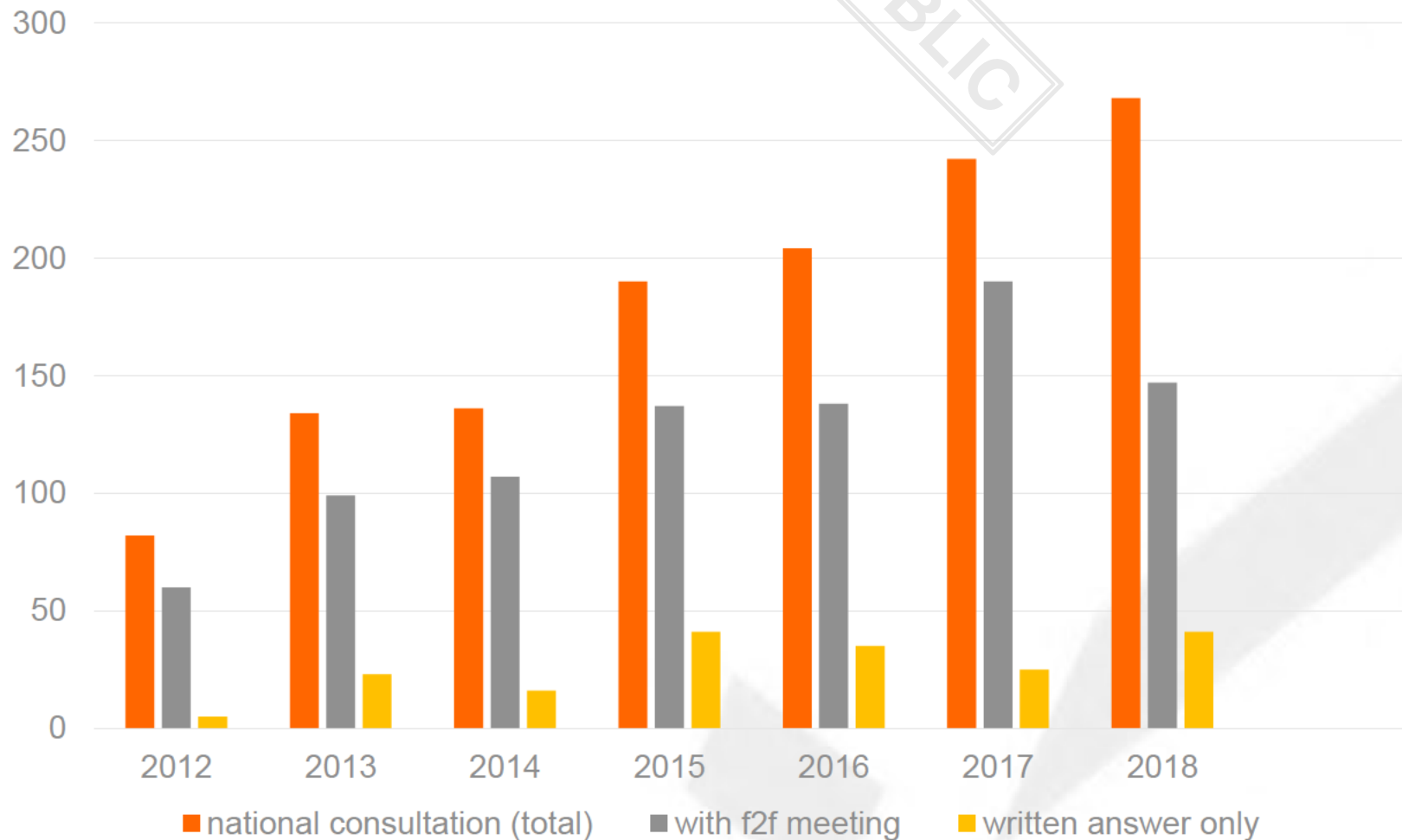
Would you participate again in an JSC?



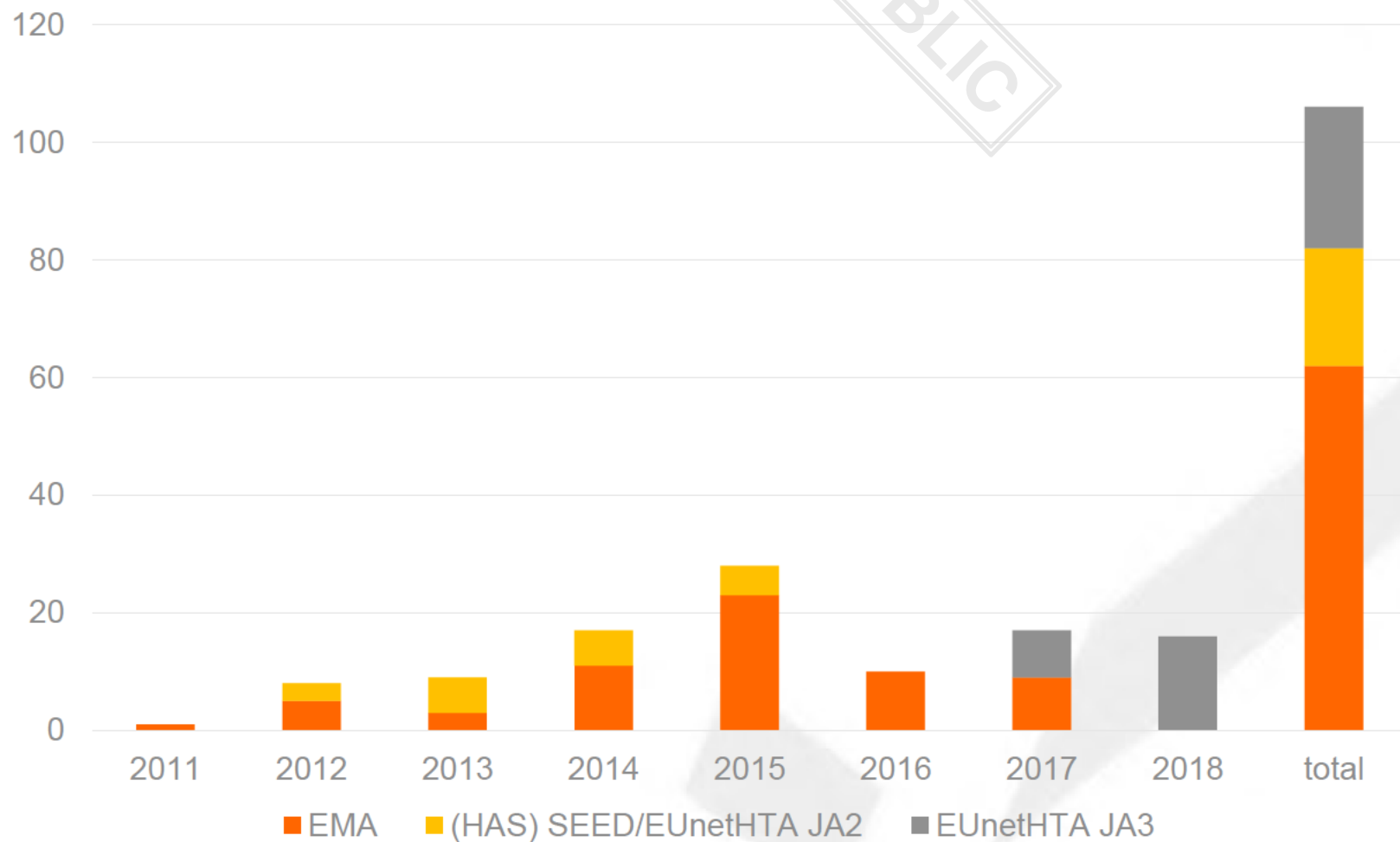
*Yes, for *specific products* that have identified gaps and issues on EGP, that are game changers, where the company has less knowledge on a given therapeutic area; decision to be made on a team basis, product by product.

**Depends on therapy

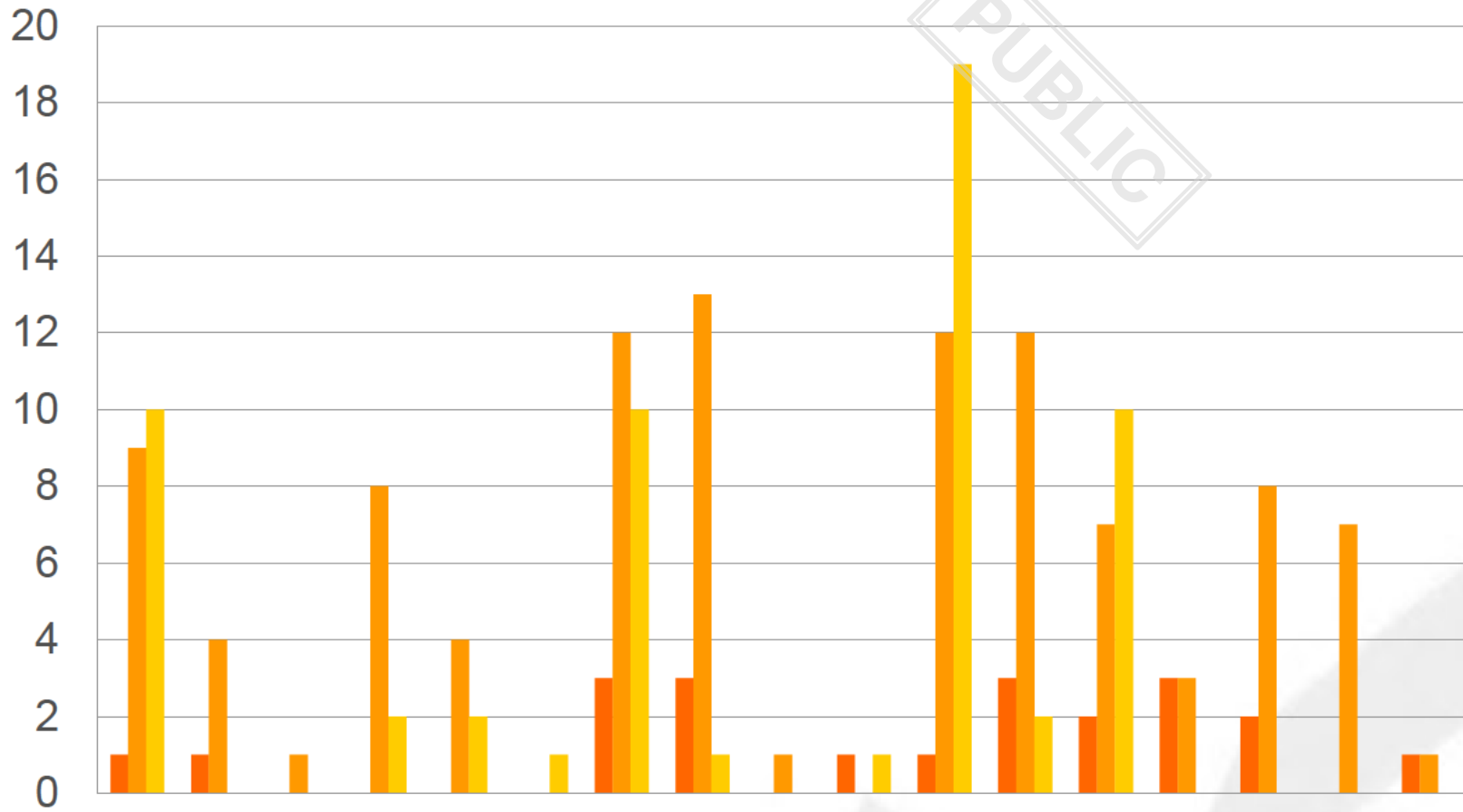
National consultations at the G-BA (as of Nov. 2018)



G-BA participation in European scientific advices (as of Nov. 2018)



HTAb participation in JSCs



PUBLIC

AEMPS
AETSA
AETS-ISCIII
AIFA
AQUAS
ATOMIT
G-BA
HAS
HVB
INFARMED
NICE
NIPN
NOMA
RER
RIZIV-INAMI
TLV
ZIN

- multi-HTA
- PCC
- PCI

Participation in JSCs to date

Parallel Consultation, high priority (PCC)/HTA only (multi-HTA)

= EUnetHTA procedures:

HTAb Participation: Max 9; Min 5; Avg. 7,3

Scientific Coordinators: HAS, G-BA, NICE, NOMA, AEMPS

Rapporteurs: G-BA, HAS, NICE

Parallel Consultation, low priority (PCI):

HTAb Participation variable, depending on the product:

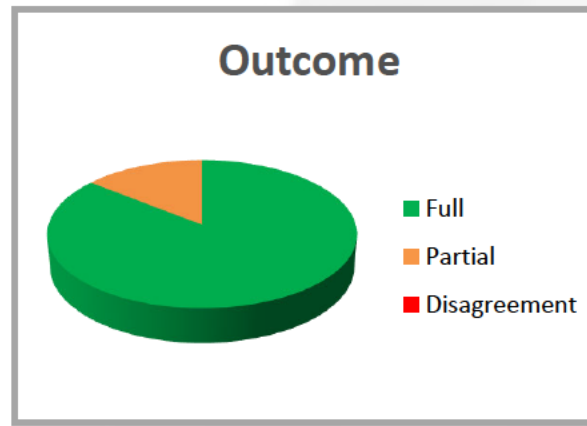
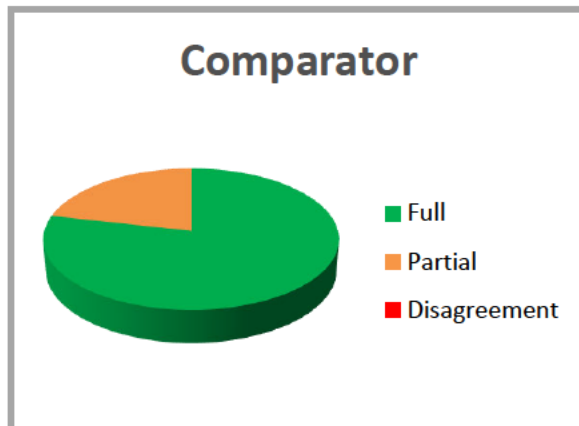
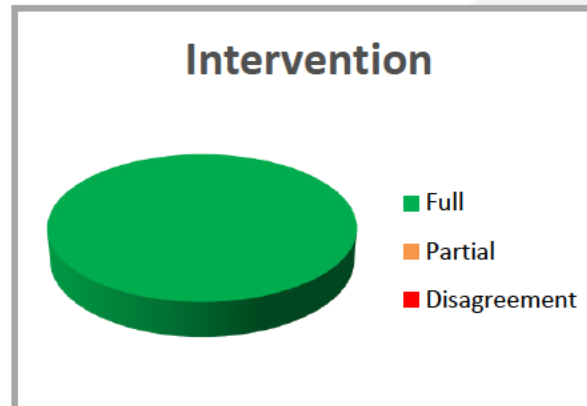
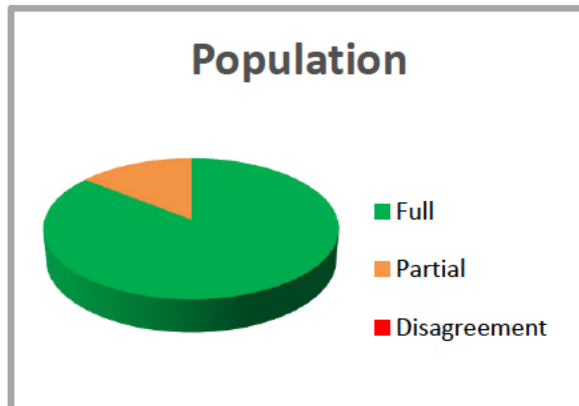
Max 5; Min 1; Avg. 2,8

Scientific Coordinators: G-BA, AEMPS, NICE, NOMA

Some partners serving only as observers for now: JAZMP, NCPHA

Alignment in JSCs between HTAb

Full agreement	HTABs provide a common response Does not prevent supplementary national specifications
Partial agreement	> 50% of HTA bodies agree on a common response
Disagreement	< 50% of HTA bodies agree on a common response

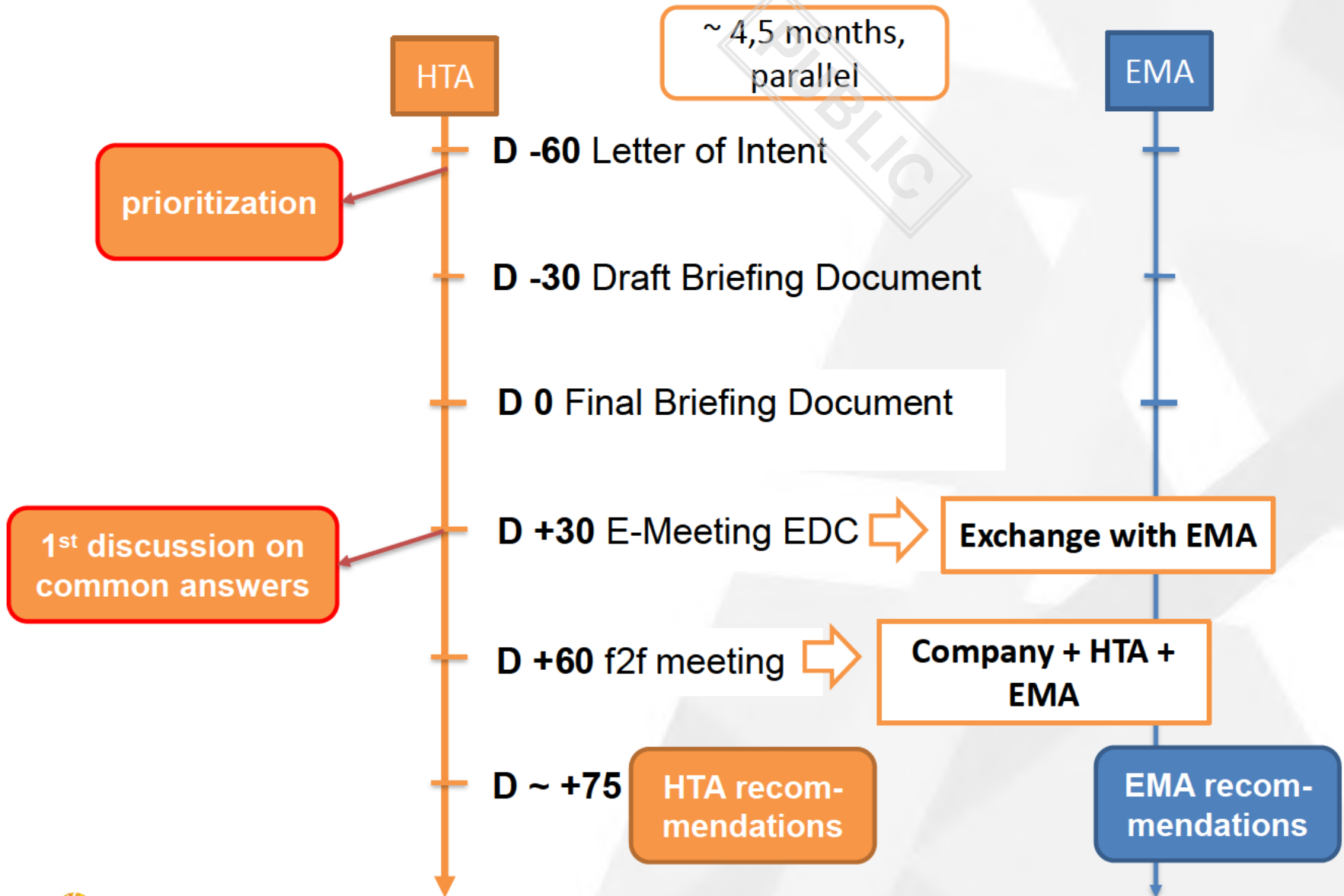


No disagreement

P = O:
full 85.7%
partial 14.3%

C:
full 78.6%
partial 21.4%

JSC timeline and procedural overview



PUBLIC

Thank you

