EU HTA:
Opportunities and Risks in a Global Environment

15th February 2019 – European Statistical Meeting

Tina Taube
Project Lead Patient Access & Global Reimbursement Regulation

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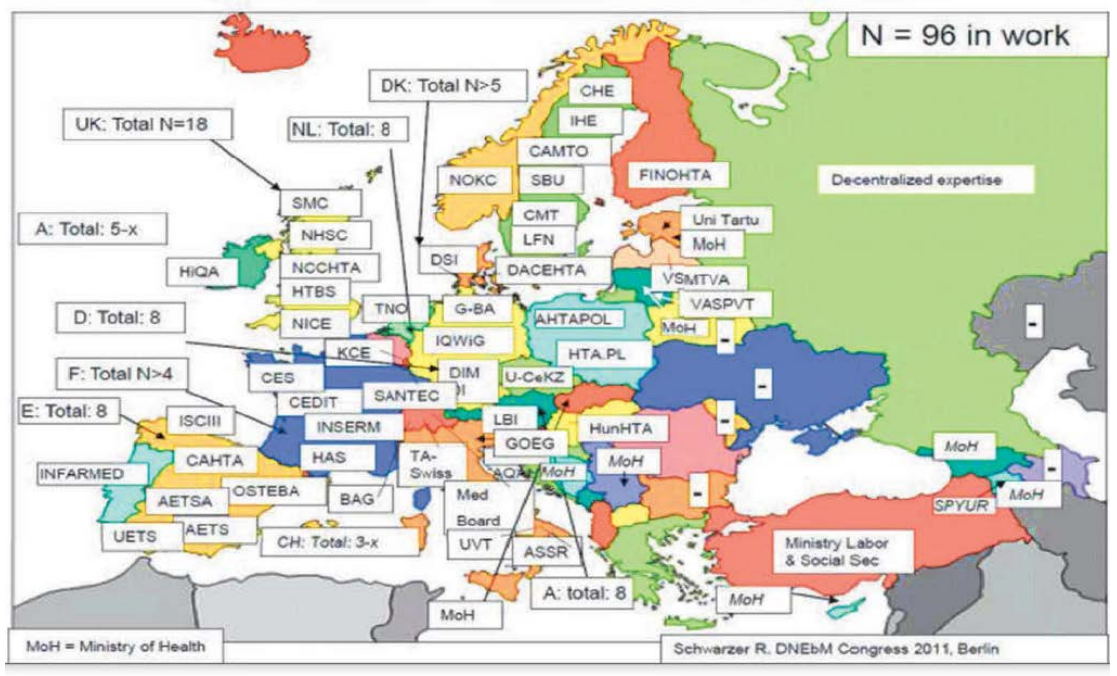
Market access in Europe is challenging due to many divergent HTA systems in place

Marketing authorisation

European Medicines Agency (EMA)

Health Technology Assessment



Source: Schwarzer R. DNEbm Congress 2011, Berlin

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European Commission is calling for joint production of HTA by 2020

Commission's viewpoint

High Level Pharmaceutical Forum (2005-2008)
Pricing & Reimbursement
Patient information
Relative Effectiveness Assessement

Joint Action

Method development for HTA; focus on REA
34 HTA agencies, 24 MS;
GER: DIMDI, IQWiG

Joint Action 2

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All MS
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2006: Establishment of EUnetHTA

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(Art. 15 HTA Cooperation)

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About EUnetHTA

- EUnetHTA was established to create an effective and sustainable network for HTA across Europe
- **“We work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries”**
- EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through
  - facilitating efficient use of resources available for HTA
  - creating a sustainable system of HTA knowledge sharing
  - promoting good practice in HTA methods and processes

Source: EUnetHTA | Note: The information on this slide were adopted in whole or in substance from the eunethta.eu website.

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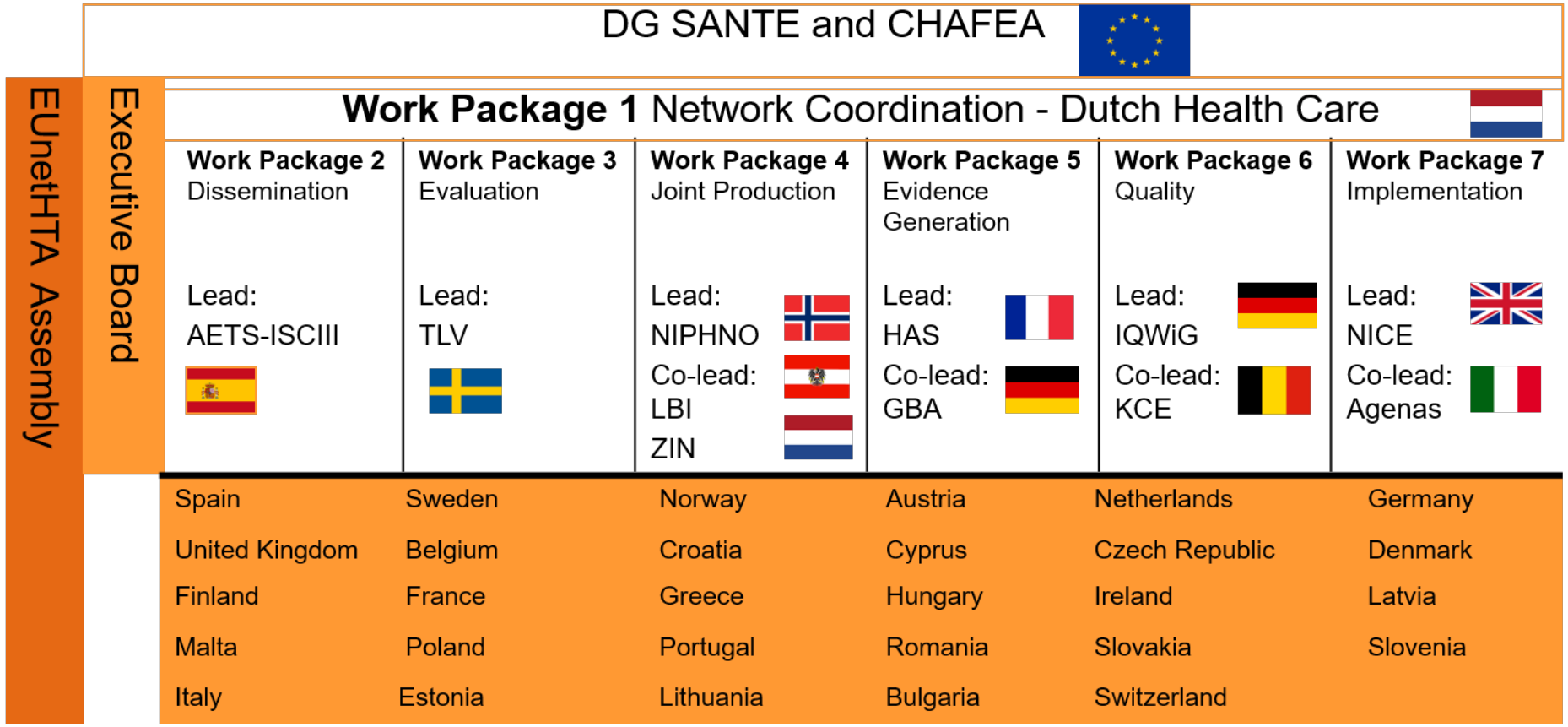
Joint Action 3: Organisational and governance structure



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Work Package 4: Current Joint Assessments

Company	Indication	Author Countries	Reviewers	Observers
Novartis	Midostaurin for the indication of Acute Myeloid Leukaemia	1st: FIMEA (FI) Co-:NOMA (NO)	TLV (SE), ZIN (NL), HAS (FR), NICE (UK), AEMPS (ES), IQWIG (DE)	UKL (CZ), SU (HU) EOPPY (EL), SESCS (ES)
Bayer	Regorafenib for patients with hepatocellular carcinoma who progressed on sorafenib treatment	1st: HAS (FR) Co-: INFARMED (PT)	AAZ (HR), SNHTA (CH), FIMEA (FI) LBI (AT), NIPN (HU), AETSA (Andalusian HTA)	EOF (EL)
Roche	Alecensa as monotherapy is indicated for the first-line treatment of adult patients with ALK+ advanced NSCLC	1st: TLV (SE) Co-: HVB (AT), AAZ (HR)	NICE (UK), Regione Veneto (IT) Uniba (SK), AETSA (Andalusian HTA) NIPN (HU)	MoH Malta
Sanofi	Sotagliflozin for Type 1 diabetes mellitus Patient Input - Diabetes Type 1	1st: TLV (SE) Co-: HVB (AT), AAZ (HR)	AEMPS (ES), SNHTA (CH), NVD (LV), INFARMED (PT), AOTMiT (PL)	HIS (UK), EOF (GR)
Celgene	Enasidenib for the treatment of adult patients with relapsed or refractory acute myeloid leukaemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation	1st: NOMA (NO) Co-: AEMPS (ES), AETSA (Andalusian HTA)	HAS (FR), AIFA (IT), SNHTA (CH), HIS (UK), DPA/MOH Malta	-/-

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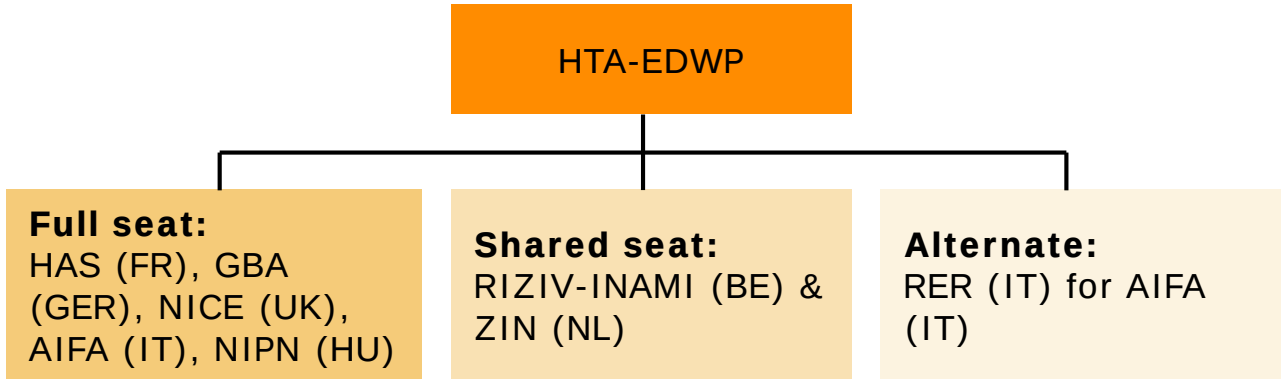
Work Package 5: Early Dialogue Working Party (EDWP)

- Permanent committee of HTA institutions with substantial experience and sufficient resources to sustain a long-term cooperation
- Coordination by EUnetHTA ED secretariat (HAS, France)
- At the moment, rotating scientific coordination by HAS & GBA (Germany)
- Potentially inclusion of one nordic (TLV/NOMA) and/ or Spanish seat



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Status Quo: 15 EUnetHTA methodology guidelines

2014

- Meta-analysis of diagnostic test accuracy studies

2015

Comparators & Comparisons

- Criteria for the choice of the most appropriate comparator(s)
- Direct & indirect comparisons

Level of Evidence

- Applicability of evidence for the context of a REA
- Internal validity of randomised controlled trials
- Internal validity of non-randomised studies on interventions

Endpoints in REA

- Safety
- Clinical endpoints
- Composite endpoints
- Surrogate endpoints
- Health-related quality of life & utility measures

- Methods for health economic evaluations - A guideline based on current practices in Europe
- Personalised Medicine and Co-dependent Technologies
- Therapeutic medical devices

2017

- Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness

2018*

- Critical assessment of clinical evaluations

2019*

- Critical assessment of economic evaluations

*not yet published

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2005-08 → 2010-12 → 2012-16 → 2016-20

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A voluntary cooperation on EU HTA cannot sufficiently address identified challenges

Despite the achievements of the current EU cooperation, a number of problems have been identified, which cannot be sufficiently addressed by continued project-based voluntary cooperation on Health Technology Assessment (HTA):

- Impeded and distorted market access
- Duplication of work for national HTA bodies
- Unsustainability of HTA cooperation

Source: COM(2018) 51 final

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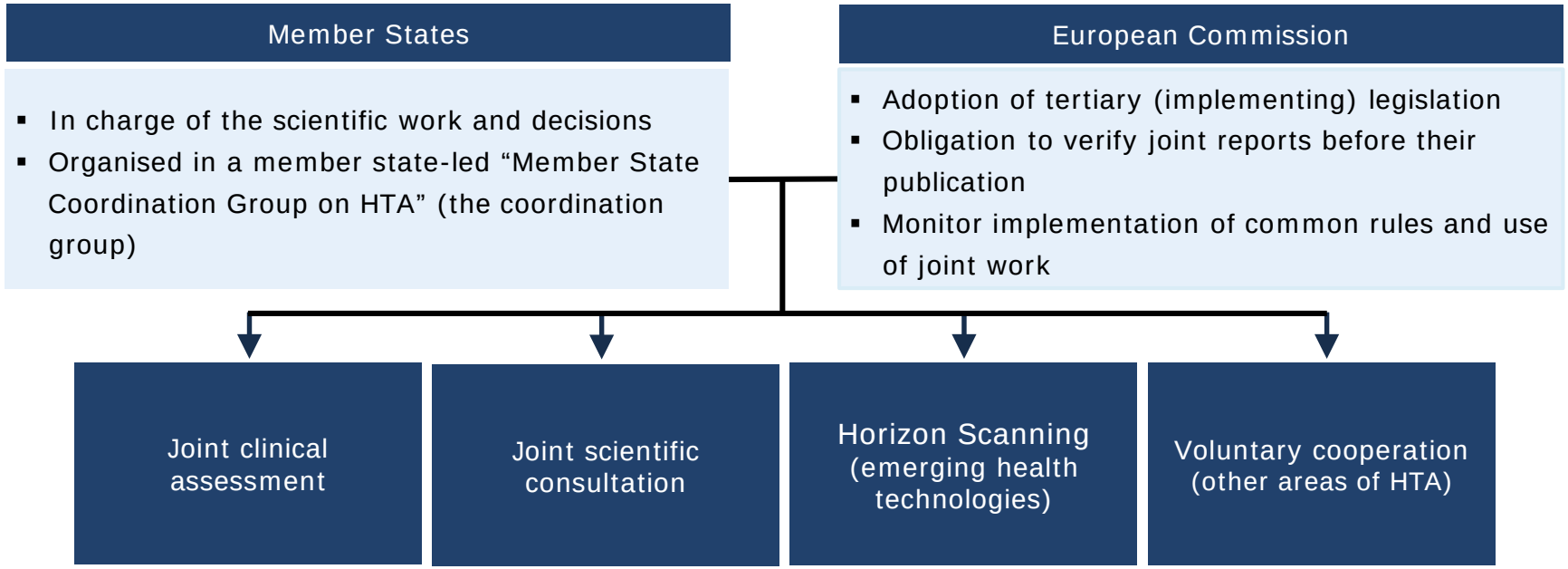
Proposal of the European Commission: Key points



Scope: EMA approved medicinal products

Medicinal products: New active substance + New indications of already approved active substance

Medical devices: Certain classifications

Timeline

HTA report should be available at the time of Commission decision for MA

Regulatory approval and HTA remain separate processes

Source: COM(2018) 51 final

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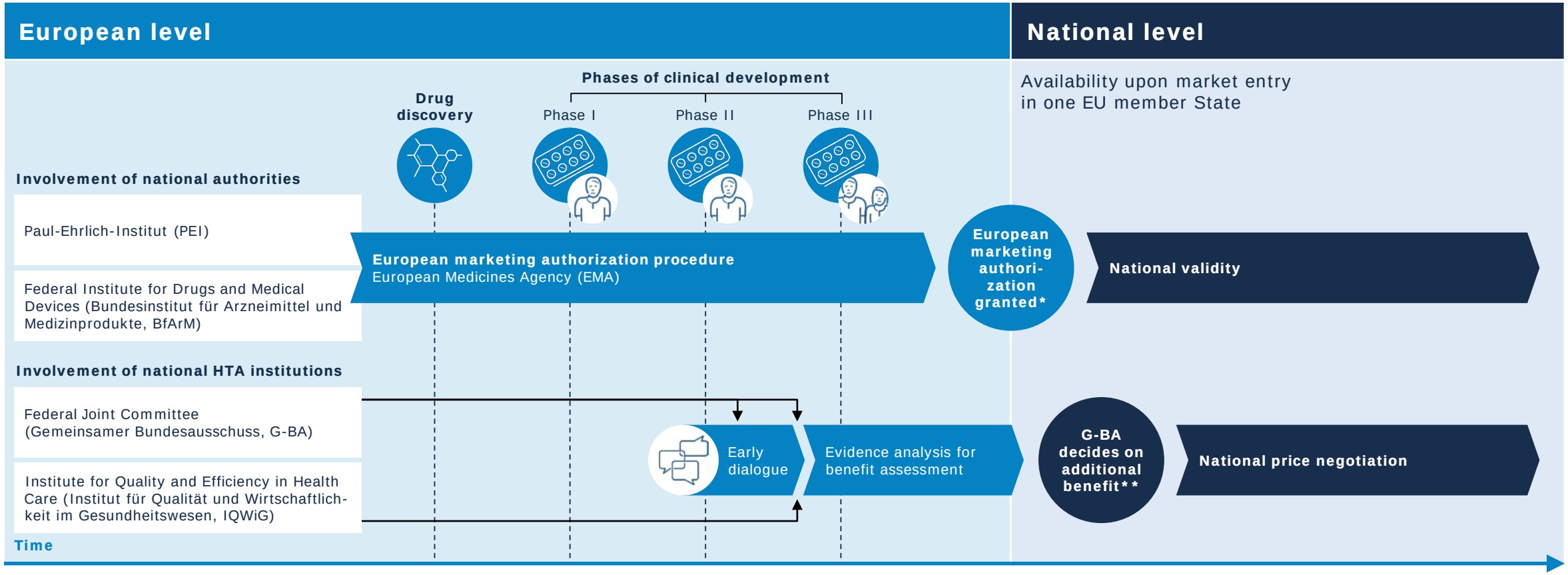
EU-HTA - a reasonable division of responsibilities between EU and Member States



* Precondition: Positive benefit-risk assessment; ** Additional benefit compared to appropriate comparator

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EU proposal is compatible with German AMNOG system

1 Fast patient access to new therapies

- No delay in AMNOG process due to harmonized timeline with marketing authorisation procedure
- Immediate market access after marketing authorisation approval and thus fast availability for patients is in line with the proposed EU model

2 Maintaining high quality standards

- Existing international cooperation of IQWiG / G-BA with EUnetHTA and EMA
- G-BA and IQWiG already strongly involved in methodology development, quality assurance and evidence generation within the voluntary European cooperation (EUnetHTA)
- IQWiG/G-BA will be part of the future coordination group

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EU proposal is compatible with German AMNOG system

3 Decision on added benefit and reimbursement remain national

- The joint clinical assessment report will focus on clinical effectiveness analysis for uptake by MS in their national reimbursement system
- Decision of additional benefit remains at the G-BA, special regulations for orphan drugs can also be applied
- GKV-SV conducts subsequent price negotiations with manufacturers

4 Definition of appropriate comparator(s)

- Country-specific considerations can be taken into account
- Participation of the G-BA in the European Coordination Group and joint scientific consultation
- Assessment can consider different appropriate comparator(s), if required by the needs of the Member States

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German industry can support the European initiative

1. Through a comprehensive European cooperation of national institutions, the respective skills and experiences can be utilized to ensure highest quality standards.
2. Improved coordination between regulatory authorities and HTA institutions reduces friction losses on necessary clinical evidence and ensures timely availability of HTA information.
3. Country-specific considerations are not a challenge, e.g. the appropriate comparator, as they could be taken into account.
4. Immediate patient access to innovative medicines will not be affected in Germany.
5. Reimbursement decisions remain a sole national responsibility.
6. From an industry perspective, effective use of the joint clinical assessment report without a repetition of the clinical assessment in the Member States' overall HTA processes is key.

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Tertiary legislation implementation
Delegated legal acts, technical preparation, cooperation

Transitional period
Participation optional, standards compulsory

EU-HTA fully implemented

2005-08 | 2010-12 | 2012-16 | 2016-20 | 3 Jahre | 3 Jahre

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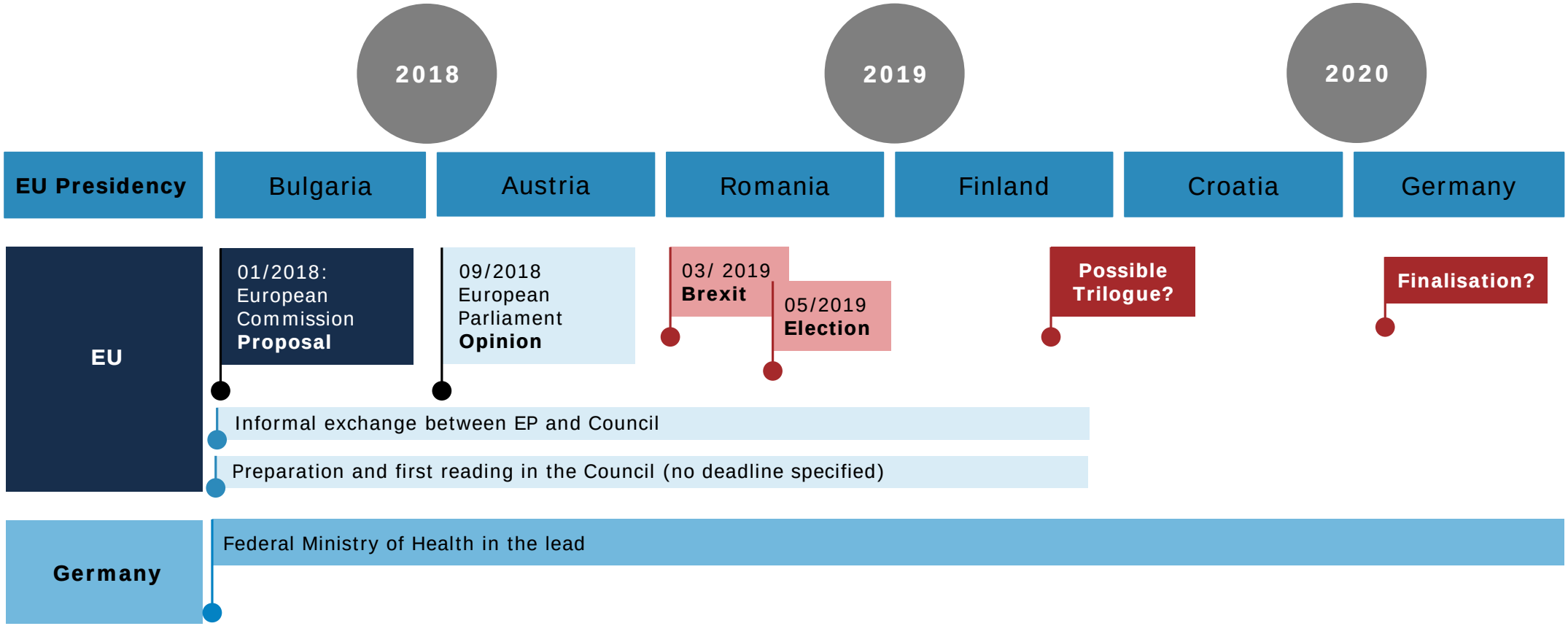
Anticipated timeline (as of January 2019)



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Thank you!

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