New EU HTA Directive Set to Revolutionize HTA in Europe – How Will it Affect You?

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30 May 2018

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Agenda

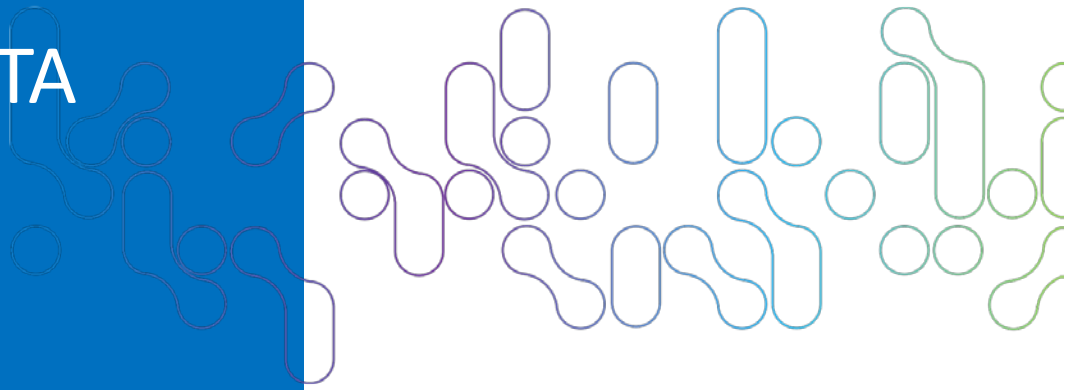
Evolution of the EU HTA Directive and stakeholder input

Key elements of the new Directive

Considerations for manufacturers

Evidera's EU HTA Working Group

Evolution of the EU HTA Directive and Stakeholder Input



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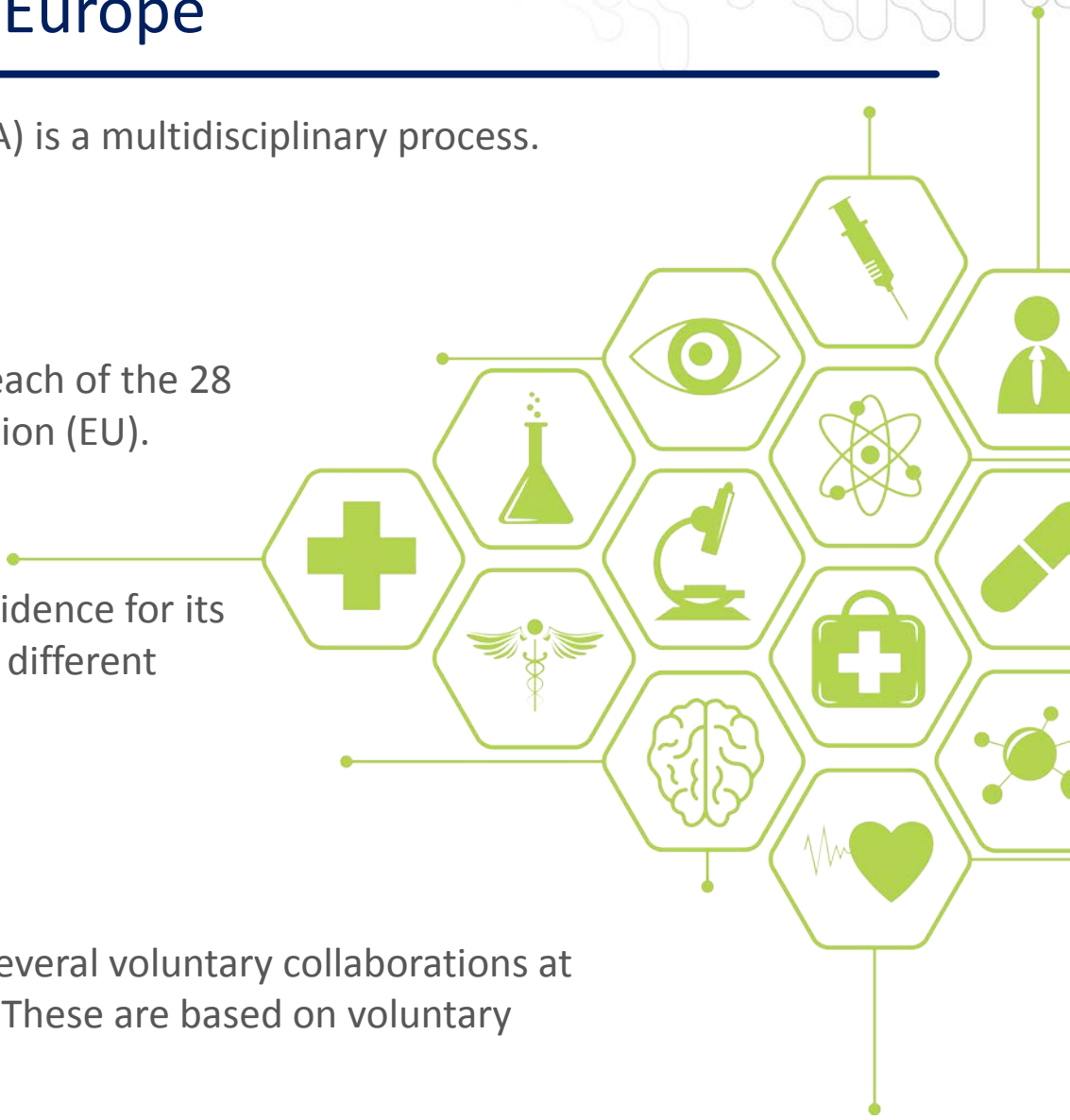
Background on HTA in Europe

- Health technology assessment (HTA) is a multidisciplinary process.
- Currently, HTAs are carried out by each of the 28 member states of the European Union (EU).
- Each country considers different evidence for its assessments, potentially leading to different outcomes and conclusions.
- Since the 1980s, there have been several voluntary collaborations at the EU level – including EUnetHTA. These are based on voluntary exchange of HTA practices.



Rationale for the EU HTA Directive

Despite the achievements of the current voluntary collaborations, several crucially remaining issues which cannot be addressed through voluntary participation[1]

IMPEDED & DISTORTED MARKET ACCESS

Differences in national processes and methodologies also lead to differences in how evidence is considered in assessments

DUPLICATION OF WORK FOR NATIONAL HTA BODIES

Clinical assessments of the same technologies are being conducted in parallel

UNSUSTAINABILITY OF HTA COOPERATION

The current union-level cooperation on HTA is project-based and funding is short-term

The EU HTA Directive was proposed to address these shortcomings:

- The development of the Directive took several years and included public consultation and impact assessment
- On 31 January 2018, the European Commission requested EU member states to adopt the new Directive[2]
  - Four countries expressed a "subsidiarity breach" but were denied due to lack of a majority
  - As of 3 April 2018, EU country parliaments have adopted the Directive[4]

1. Page 1 and 2: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf
2. https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf
3. https://pink.pharmaintelligence.informa.com/PS122940/Germany-and-France-Round-On-European-Commission-HTA-Cooperation-Proposals
4. https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

The EU HTA Directive Sets Out Four Pillars of Work

AREAS OF JOINT HTA COOPERATION

1. **Joint clinical assessments (JCA)**
2. Scientific consultations on the development of new products
3. Mapping of emerging health technologies
4. Voluntary cooperation on other areas (e.g., surgical procedures)

JOINT ASSESSMENTS

Pharmaceuticals

Clinical assessments (benefits compared to existing treatments)

All EMA approved pharmaceuticals (including line extensions/new indications)

Medical devices and diagnostics

Clinical assessments (benefits compared to existing treatments)

High-risk devices with high impact on patients, public health and EU health systems

Member states shall not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies.

NATIONAL ASSESSMENTS

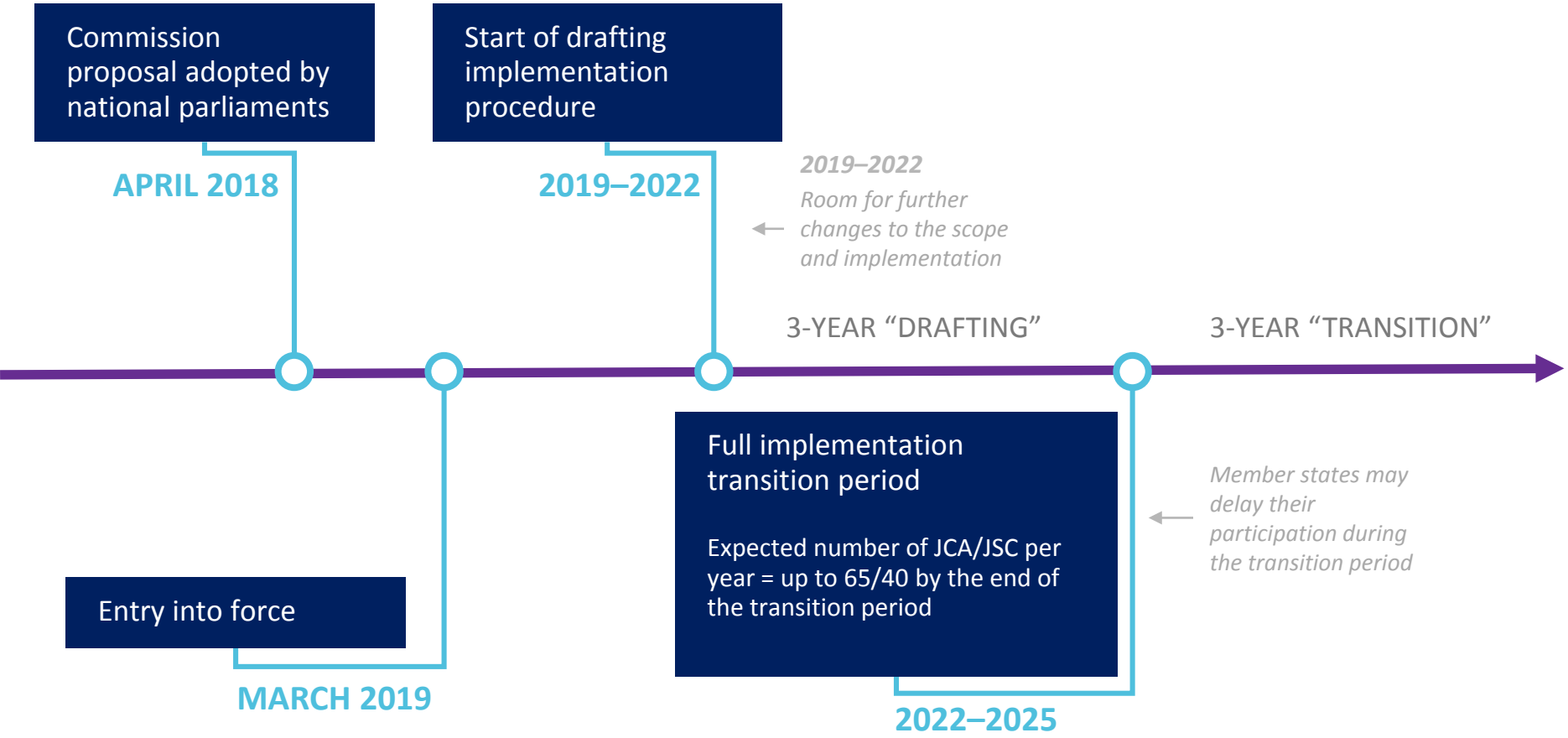
Non-clinical assessment and national decisions on price and reimbursement

RELATIONSHIP TO EMA

Opportunity for a closer alignment between the regulatory process and the HTA process.

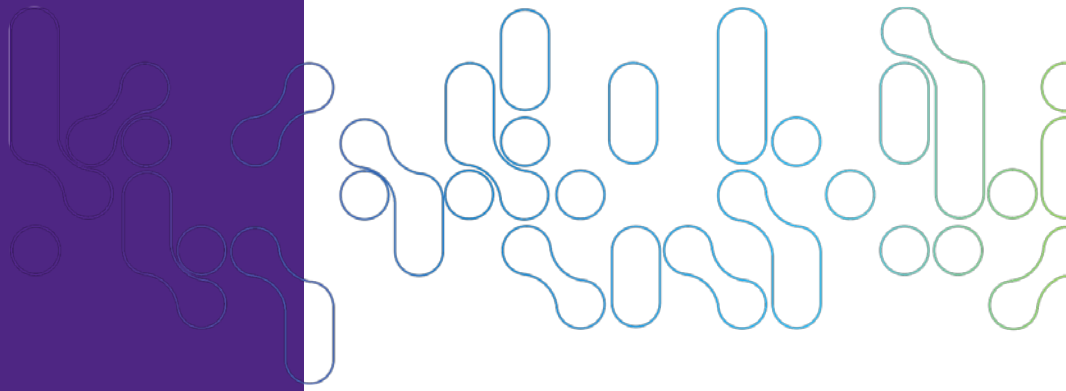
https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

The Next Steps: Three-year Drafting and 3-year Transition



1. Abbreviations: JCA = joint clinical assessment; JSC = joint scientific consultation
Articles 33 and 36 https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

Key Elements of the New Directive



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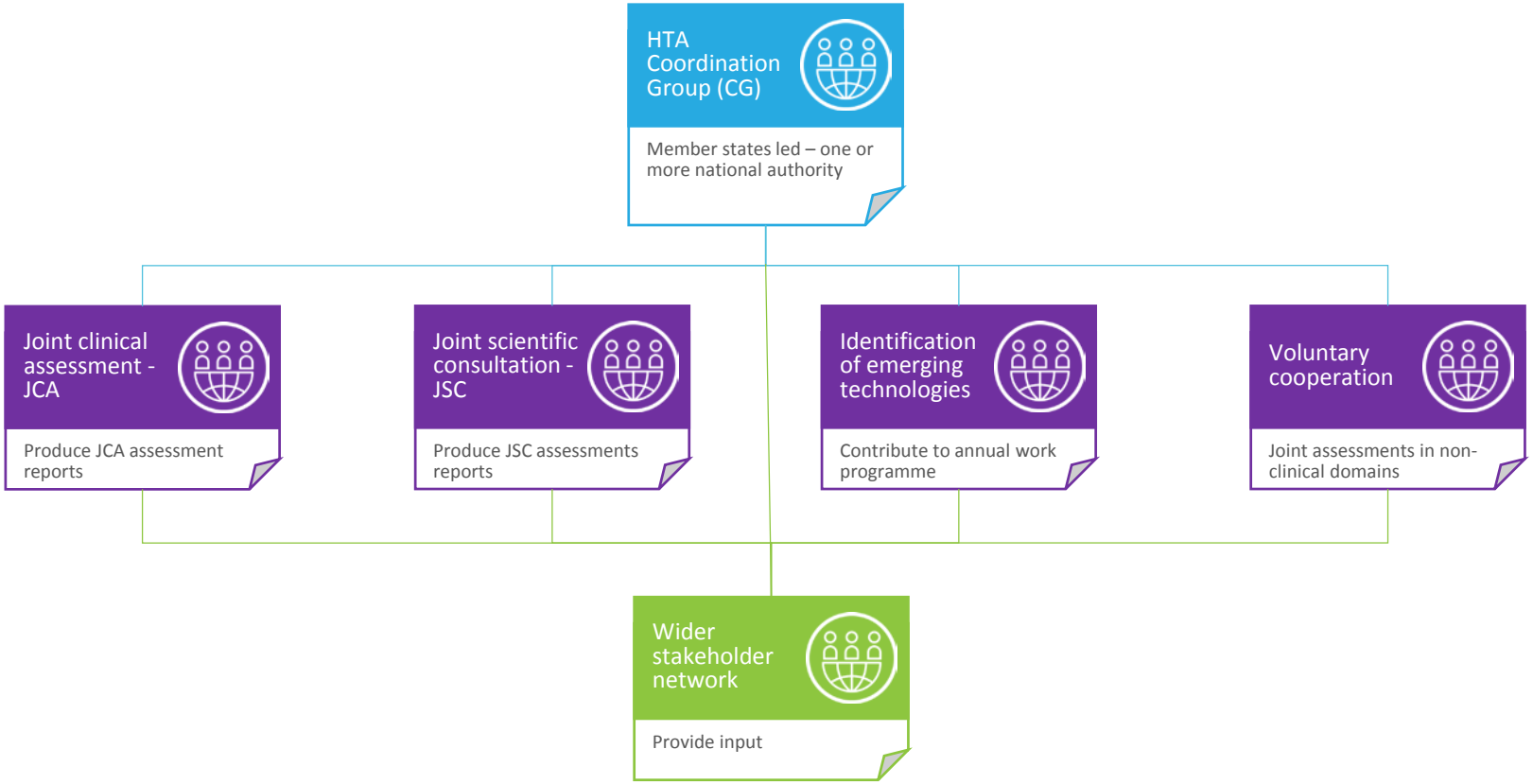
A New Structure to Deliver on the Four Areas of Joint Cooperation



European Commission will provide a secretariat

Meeting support | Technical support | IT support | Monitor compliance and uptake

https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

Role of the HTA Coordination Group (CG)

- ✓ Manage the overall governance of the joint cooperation
- ✓ Develop overall work programme including identification of emerging health technologies and setting up the timeframe of JCAs at the time of product's market launch
- ✓ Provide "early dialogues" with manufacturers, if requested (joint scientific consultation)
- ✓ Conduct updates of JCAs where: (a) the decision to grant the marketing authorisation of a product was conditional on the fulfilment of additional post-authorisation requirements; (b) the initial JCA report specified the need for an update once additional evidence for further assessment is available. The CG may carry out updates of JCAs where requested by one or more of its members.

CG COMPOSITION

Will be Member state-led and may include one or more national authorities

Page 12: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

CG Role in monitoring Emerging Technologies

- ✓ Conduct “horizon scanning” in emerging technologies expected to have a major impact on patients, public health, or healthcare systems
- ✓ Identify emerging technologies at an early stage in development and facilitating prioritisation of technologies for JCAs
- ✓ Consolidate input from different stakeholders

Page 13 and 19: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf
Presentation 9 Feb 2018; DG SANTE - Health Systems and Products, Medical Products: safety, quality, innovation

Role of the Joint Clinical Assessment (JCA) Sub-group

- ✓ Will be appointed by CG
- ✓ Focus on **comparative clinical assessment** of technology under appraisal:
  - Pharmaceuticals with EMA approval, new indications for existing substances
  - Medical devices class IIB and III*
  - In vitro diagnostic medical devices – class D**
- ✓ No assessment will be made on:
  - Price and reimbursement assessment
  - Economic assessment
- ✓ Preparation of JCA reports
  - Quality of life evaluation

Member states (after the end of transition period [2022–2025]):
Participation in the assessments and use of the JCA reports will be mandatory

*Class IIb: class IIb devices are generally medium to high risk and will often be devices installed within the body for periods of 30 days or longer. Examples include ventilators and intensive care monitoring equipment; Class III devices are strictly high risk devices. Examples include balloon catheters, prosthetic heart valves, pacemakers, etc.
** Class D: devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation

Articles 5 to 11 and page 28 https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

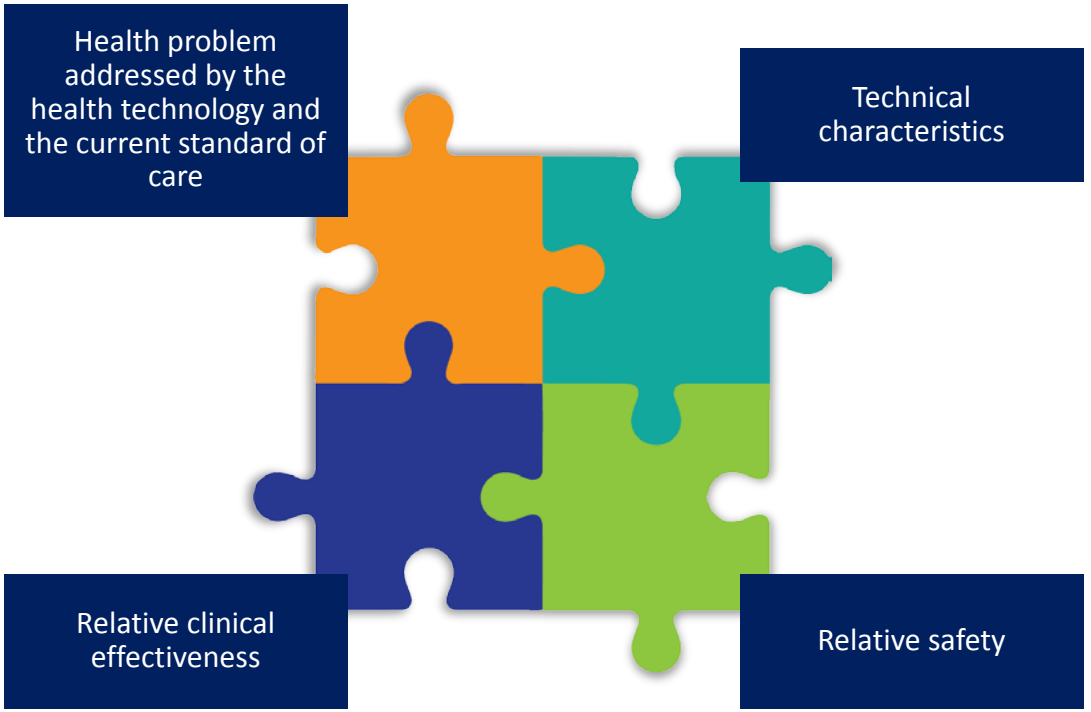
JCAs Involve Comparisons with One or More Technologies

Key element – Clinical assessments are comparative

- Clinical assessment means a compilation and evaluation of the available scientific evidence on a health technology in comparison with one or more other health technologies, based on the following clinical domains:

The conclusions of the joint comparative clinical assessment report shall be limited to:

- An analysis of the ***relative effects*** of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment
- The ***degree of certainty*** on the relative effects based on the available evidence



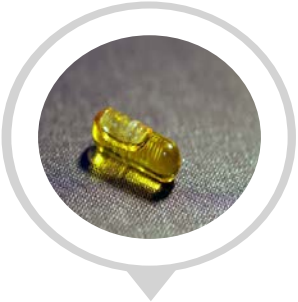
Page 22 https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

Selection Criteria for JCAs

PHARMACEUTICALS

MEDICAL DEVICES CLASS IIB AND III

IN VITRO DIAGNOSTIC MEDICAL DEVICES – CLASS D



PHARMACEUTICALS
All EMA approved

SELECTION CRITERIA (ALL TECHNOLOGIES)

- Unmet medical needs
- Potential impact on patients, public health, or healthcare systems
- Significant cross-border dimension
- Major union-wide added value
- Available resources

SELECTION CRITERIA (MEDICAL DEVICES)

- New criteria will exist
  - For pharmaceuticals and others
  - Criteria to be determined

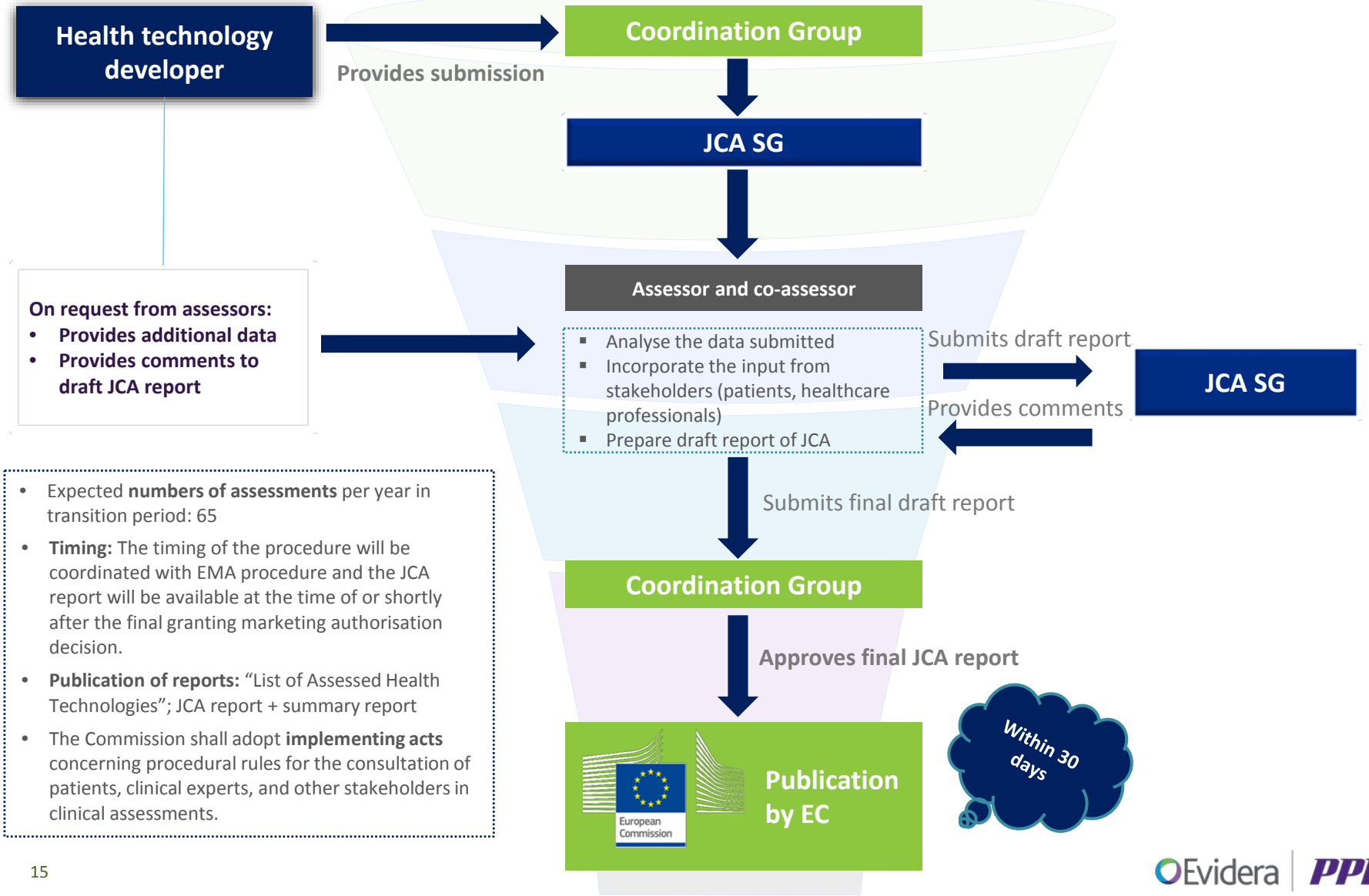
2022 2023 2024 2025 2026 and beyond

TRANSITION PERIOD

Expected numbers of assessments per year in transition period: 65

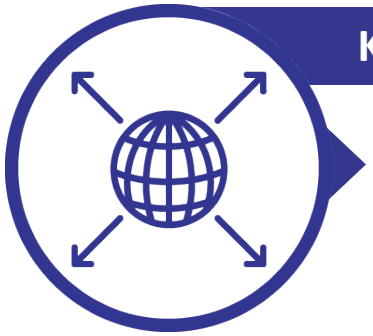
Articles 5 to 11 https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

Preparation of JCA Reports



- Expected **numbers of assessments** per year in transition period: 65
- **Timing:** The timing of the procedure will be coordinated with EMA procedure and the JCA report will be available at the time of or shortly after the final granting marketing authorisation decision.
- **Publication of reports:** "List of Assessed Health Technologies"; JCA report + summary report
- The Commission shall adopt **implementing acts** concerning procedural rules for the consultation of patients, clinical experts, and other stakeholders in clinical assessments.

Implementation of JCAs



Implementation of member states

KEY ELEMENT – NO DUPLICATION AT NATIONAL LEVEL

Member states shall:

- Not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which JCA has been initiated
- Apply JCA reports in their health technology assessments at member state level

Caveat: during the three-year transition period, member states can delay their participation

- would have the option to delay their participation in the joint work on clinical assessments and scientific consultations
- would not be obliged to use the output of this joint work at member state-level but would be obliged to use the common rules for their own clinical assessments
- would not be able to delay their participation partially (i.e., for only one category of health technology or for only one part of the joint work).

Article 8 and page 12 and 14 https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

CG Role in Joint Scientific Consultations

- ✓ Manufacturers can make a request to CG for an “early dialogue” during the development phase of a health technology.
- ✓ These consultations can include only HTAs or EMA and HTAs in parallel. During the transition period it is anticipated that 40 consultations will be conducted.
- ✓ Aim of these consultations would be for manufacturers to seek advice on the data likely to be required for a potential future JCA.
- ✓ Number of JSCs to be set during CG annual programme, depending on the resources availability.
- ✓ Process would be the same as JCAs but the final report approved by CG will not be published and will have an advisory role for manufacturers (by that meaning that manufacturers won’t be obliged to follow this advice in future JCAs).

Voluntary Cooperation

Member states can continue cooperation on voluntary basis at Union-level for:

- Non-clinical assessments (for example impact of medical devices on organisational care)
- Medical devices not selected for JCAs
- Methodology and research, such as methods for the use of real-world evidence to reduce uncertainty in relative effects, the evaluation of new technologies ("ehealth", personalised medicine)
- CG shall facilitate this cooperation

Key Summary Points about EU HTA Directive

EU HTA

Includes JCA for all pharmaceuticals that are approved by the EMA

NATIONAL ASSESSMENTS

Shall not repeat clinical assessments but carry out health economic, societal, and ethical assessments and pricing

TIMING

Will come into effect in 2019 with a three-year drafting and another three-year transition period. During transition ~65 cases* should go through JCA

PROCESS

JCAs will be executed by nominated assessors and co-assessors, with strong stakeholder participation

* Medical devices and pharmaceuticals

Uncertainties Surrounding New Directive

In May 2018, many questions remain:

PROCESS

- How assessors will be determined in Member States
- Timelines of the JCA process

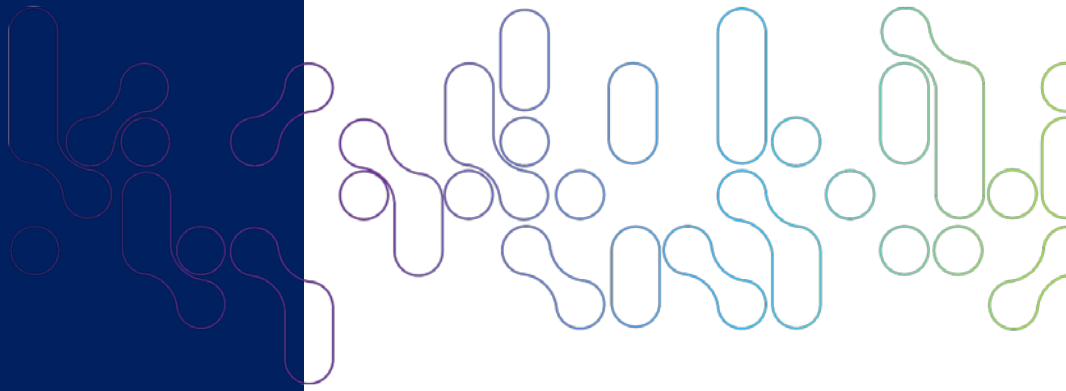
METHODS

- JCA methods and their definitions
- How the comparators will be selected
- Roles of RWE and PROs

ADOPTION

- How Member States will "adopt" JCA decisions or consider scientific advice for national assessments
- How Member States will incorporate assessments in health economics, pricing, and level of reimbursement

Considerations to Manufacturers



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Uncertainties Manufacturers Should Prepare For

PRIORITIES FOR EVIDENCE DEVELOPMENT PLANNING

KEEP UPDATED
Adjustments in evidence development planning may be required as clarity around methods is provided

PORTFOLIO
Pipeline products as well as new indications likely to be impacted

TIMING
Prepare for dual clinical assessments during transition period

STRATEGY
Early scientific advice is changing in the new environment – shift to EU facilitation

EXPERTISE
Shift of country level expertise to health economics, patient data and price/contracting

PRICE
Prepare for national price negotiation based on EU assessed clinical data

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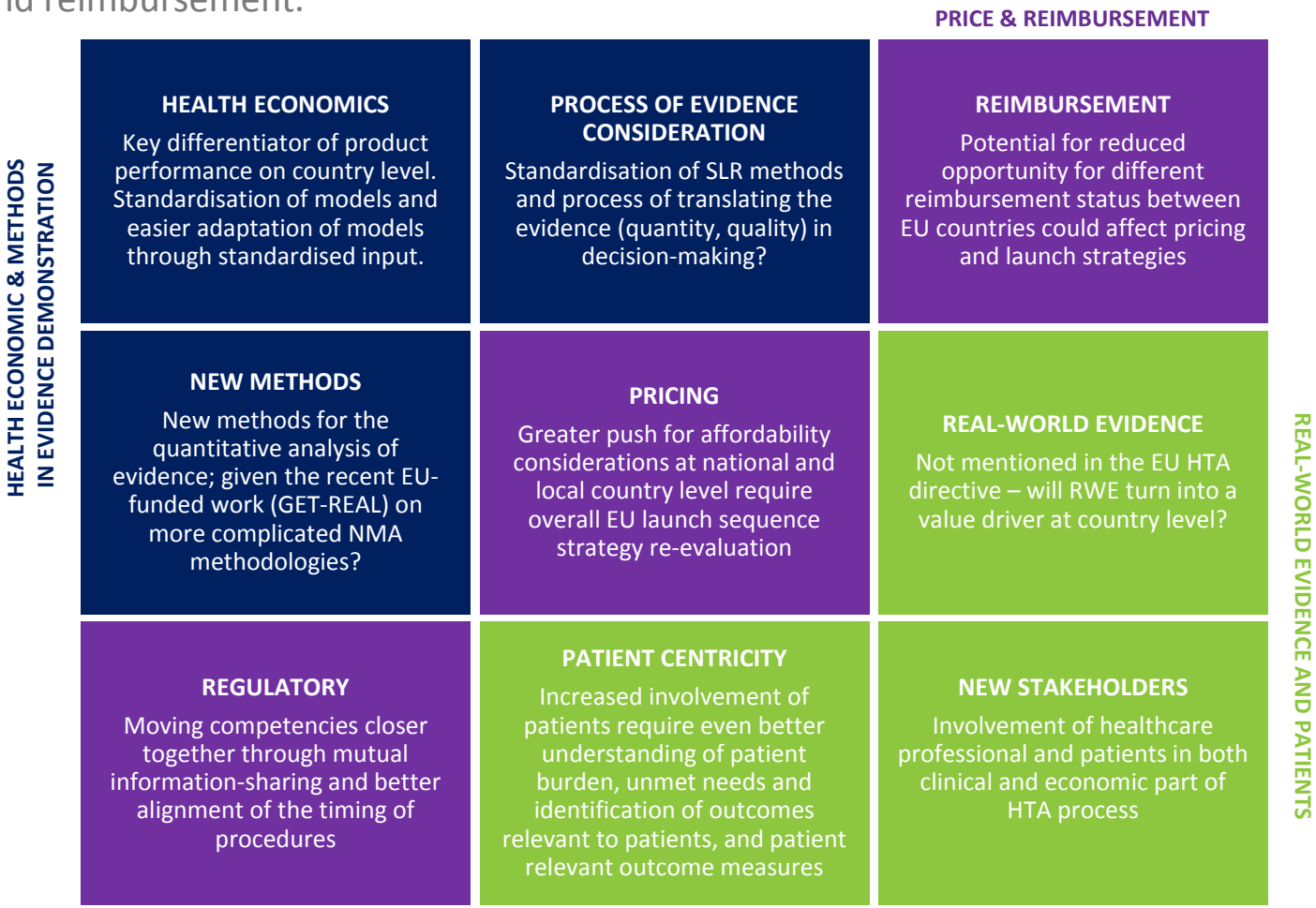
How New Priorities May Inform New Paradigms in Evidence Development

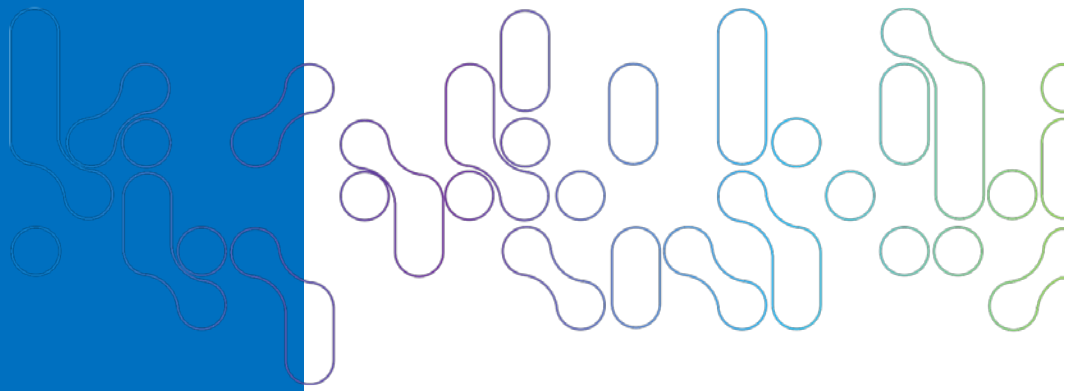
While overall strategic planning is important, immediate considerations need to be given to how the EU HTA application may create new paradigms in evidence development and implications on price and reimbursement.



Abbreviations: HTA = health technology assessment; NMA = network meta-analysis; RWE = real-world evidence; SLR = systematic literature review

https://www.imi-getreal.eu/Portals/1/Documents/Publications%20website/Including%20Real%20World%20Evidence%20in%20network%20meta-analysis.pdf

EU HTA Working Group



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EU HTA Working Group

The Evidera EU HTA Working Group comprises methodological experts and thought leaders from across our core disciplines. The aim of the working group is to keep up-to-date on the EU HTA Directive and its implications to enhance our flexible and integrated response to evolving client priorities.

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