INAMI-RIZIV

Joint Health Technology Assessment in Europe: today and tomorrow

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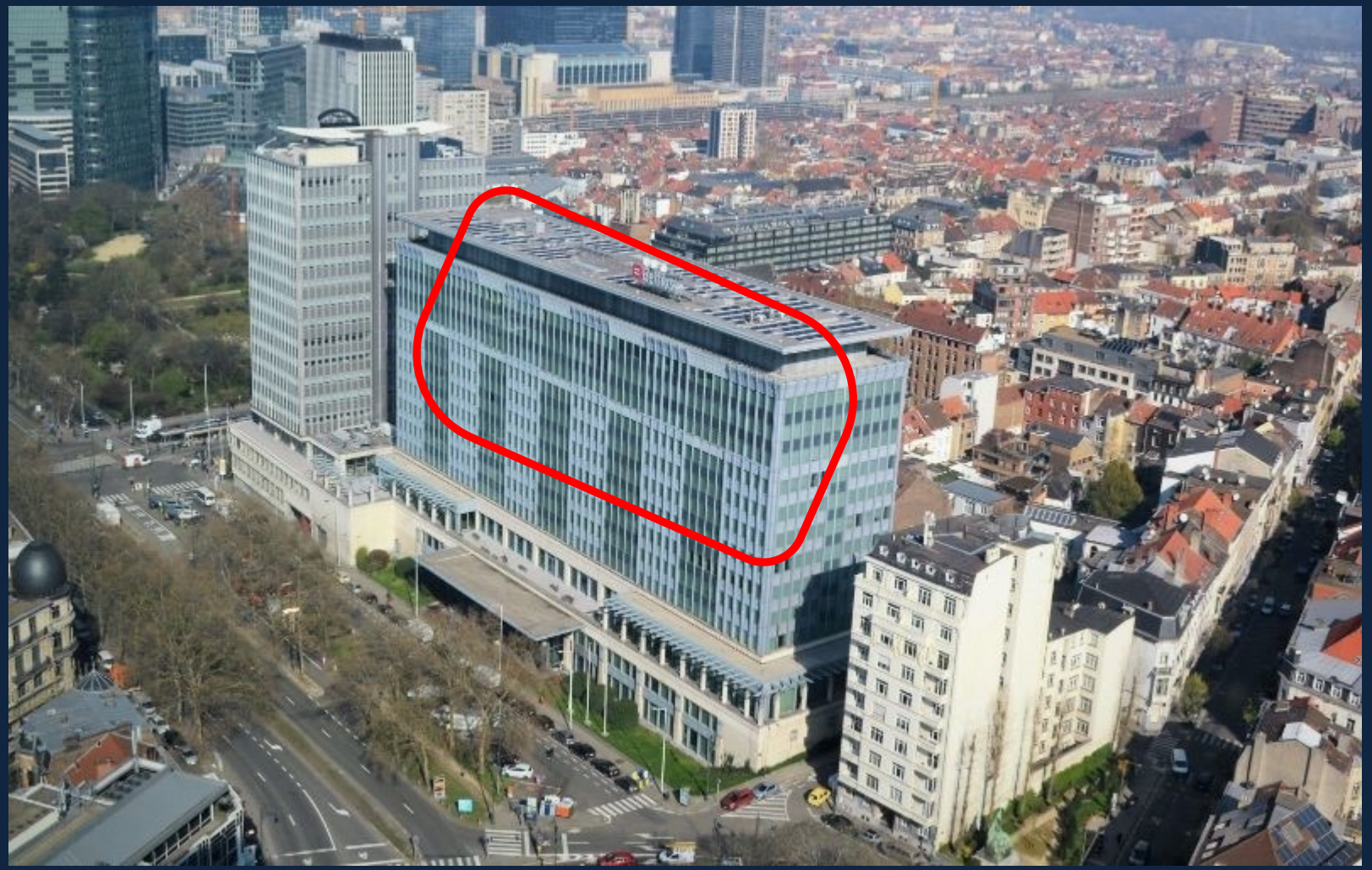
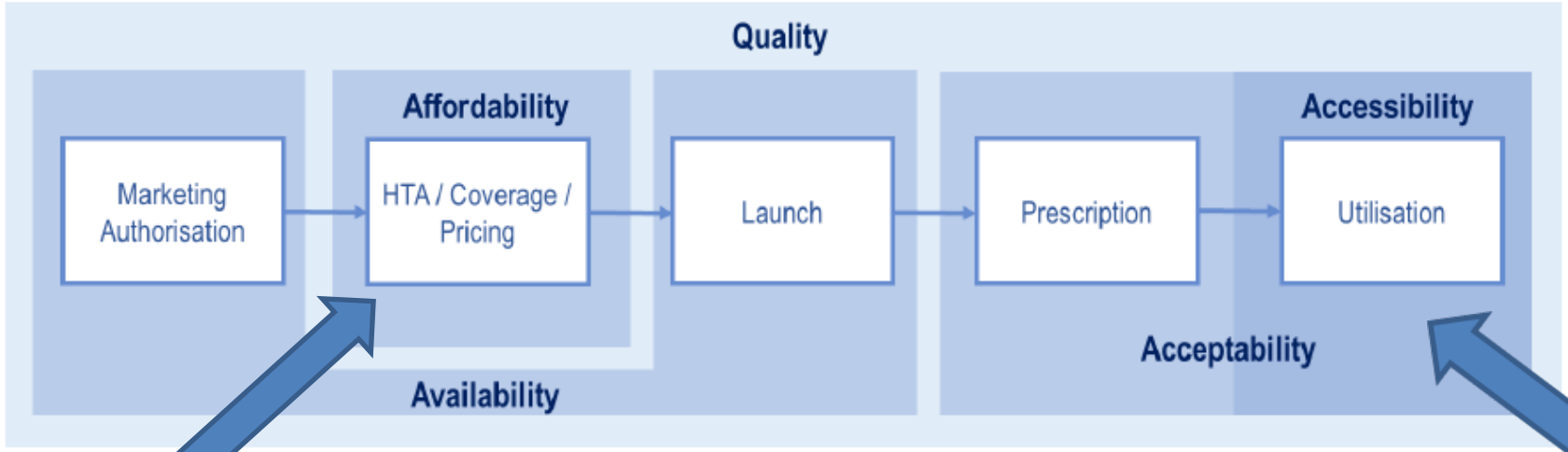


RIZIV NL
INAMI FR
LIKIV DE
NIHDI EN

Disclaimer: legal terms rephrased for this presentation

Figure 1.2. Dimensions of access relative to the lifecycle of a medicine



Note: HTA hea[illegible]echnology assessment. Dimensions of access cannot be considered mutually exclusive.
Source: Au[illegible].

OECD Health Working Papers n° 151 - 2023

HTA = Health Technology Assessment

European Public Assessment Report ***Regulatory procedure***	**Health Technology Report (HTA)** ***Reimbursement procedure***
Benefit/Risk	Therapeutic value as compared to alternatives
Absolute therapeutic value	Relative therapeutic value
+ quality of the medicine	+ added therapeutic value or not
	+ place in medical practice
	+ budget impact & cost-effectiveness

Until yesterday …

European Public Assessment Report ***Regulatory procedure***	**Health Technology Report (HTA)** ***Reimbursement procedure***
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European

National (subnational)

History Joint HTA work

2010 - 2021

HTA = Health Technology Assessment

History Joint HTA work

2010 - 2021

European agencies discuss relative effectiveness

The European Medicines Agency (EMA) is collaborating with the European network for Health Technology Assessment (EUnetHTA) to determine how it can contribute to assessments of relative effectiveness.

NATURE REVIEWS | DRUG DISCOVERY

HEADLINE NEWS

New EU HTA guideline tackles thorny issue of comparators

International Journal of Technology Assessment in Health Care, 30:5 (2014), 521–529.

doi:10.1017/S0266462314000622

PILOTING INTERNATIONAL PRODUCTION OF RAPID RELATIVE EFFECTIVENESS ASSESSMENTS OF PHARMACEUTICALS

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Zorginstituut Nederland & Summaryx Ltd

Piia Rannanheimo
Finnish Medicines Agency

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2021 legal start European HTA

22.12.2021 EN Official Journal of the European Union L 458/1

I

(Legislative acts)

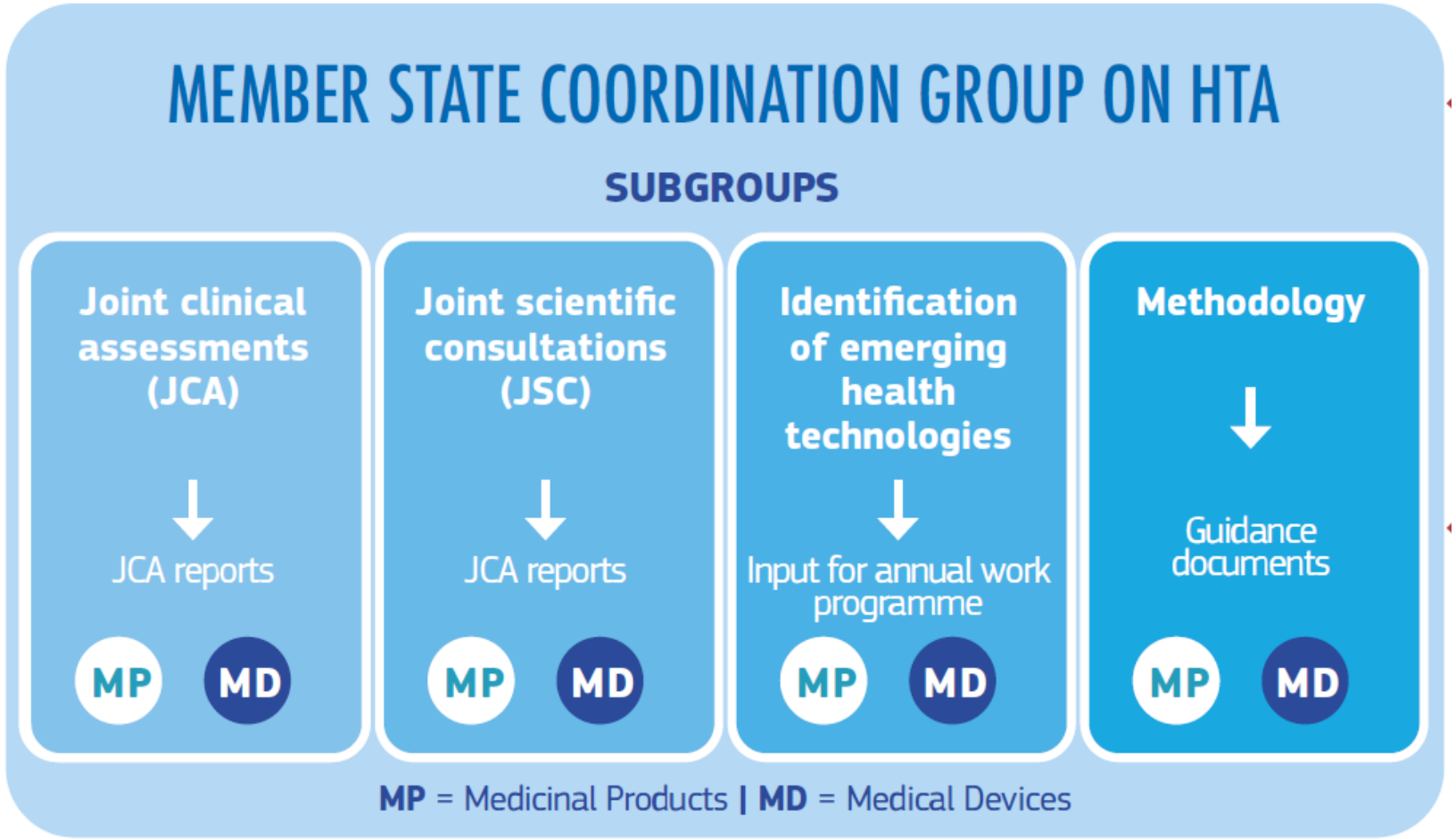
REGULATIONS

REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 December 2021
on health technology assessment and amending Directive 2011/24/EU

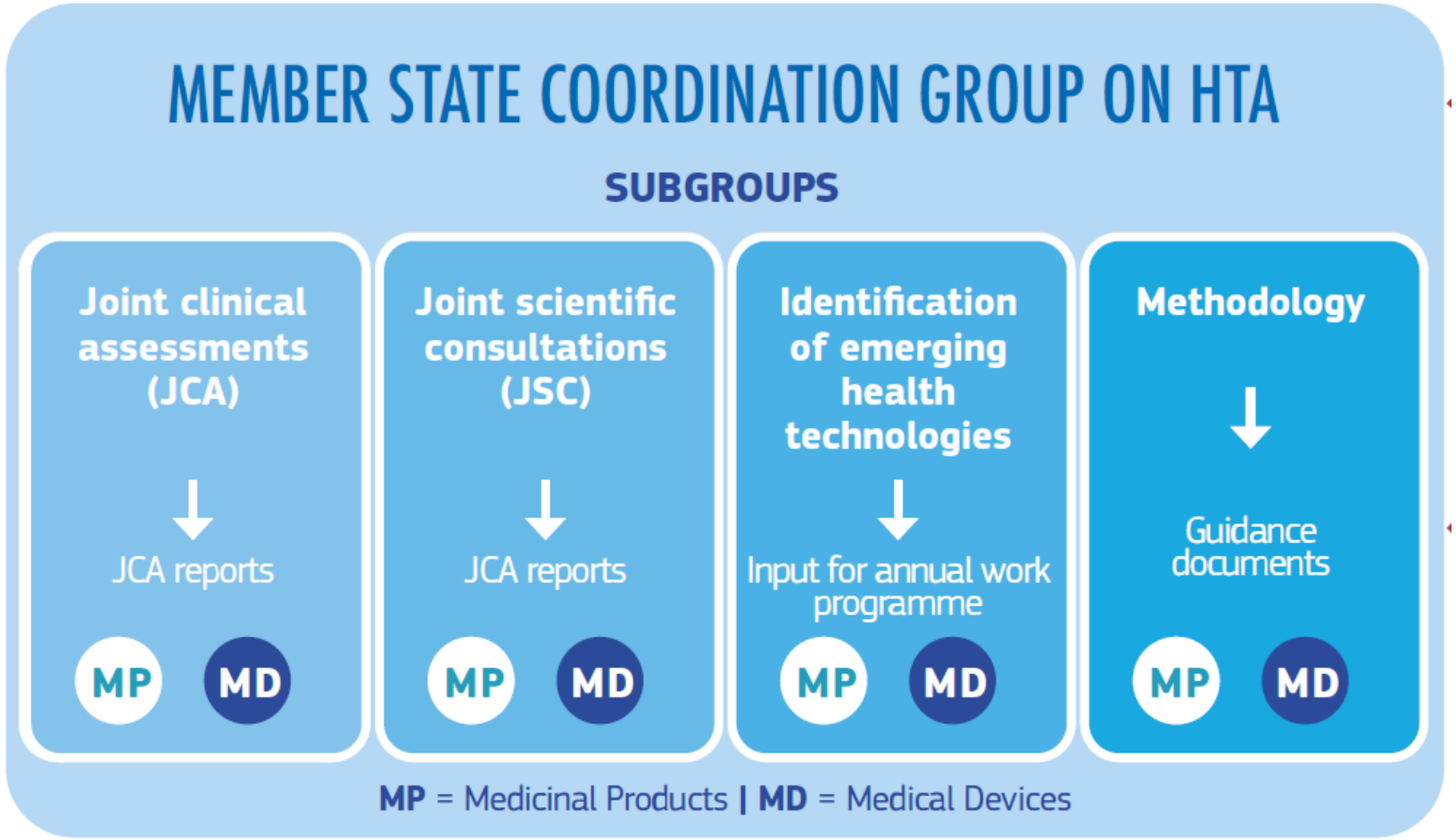
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

From 2024 on


MEMBER STATE COORDINATION GROUP ON HTA
SUBGROUPS
Joint clinical assessments (JCA)
JCA reports
MP
MD
Joint scientific consultations (JSC)
JCA reports
MP
MD
Identification of emerging health technologies
Input for annual work programme
MP
MD
Methodology
Guidance documents
MP
MD
MP = Medicinal Products | MD = Medical Devices

From 2024 on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EU HTA Coordination Group & subgroups pharmaceuticals

Francis Arickx

CG

Consortium

Comitology

Lisa Vervueren

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Consortium

Marc Van de Casteele

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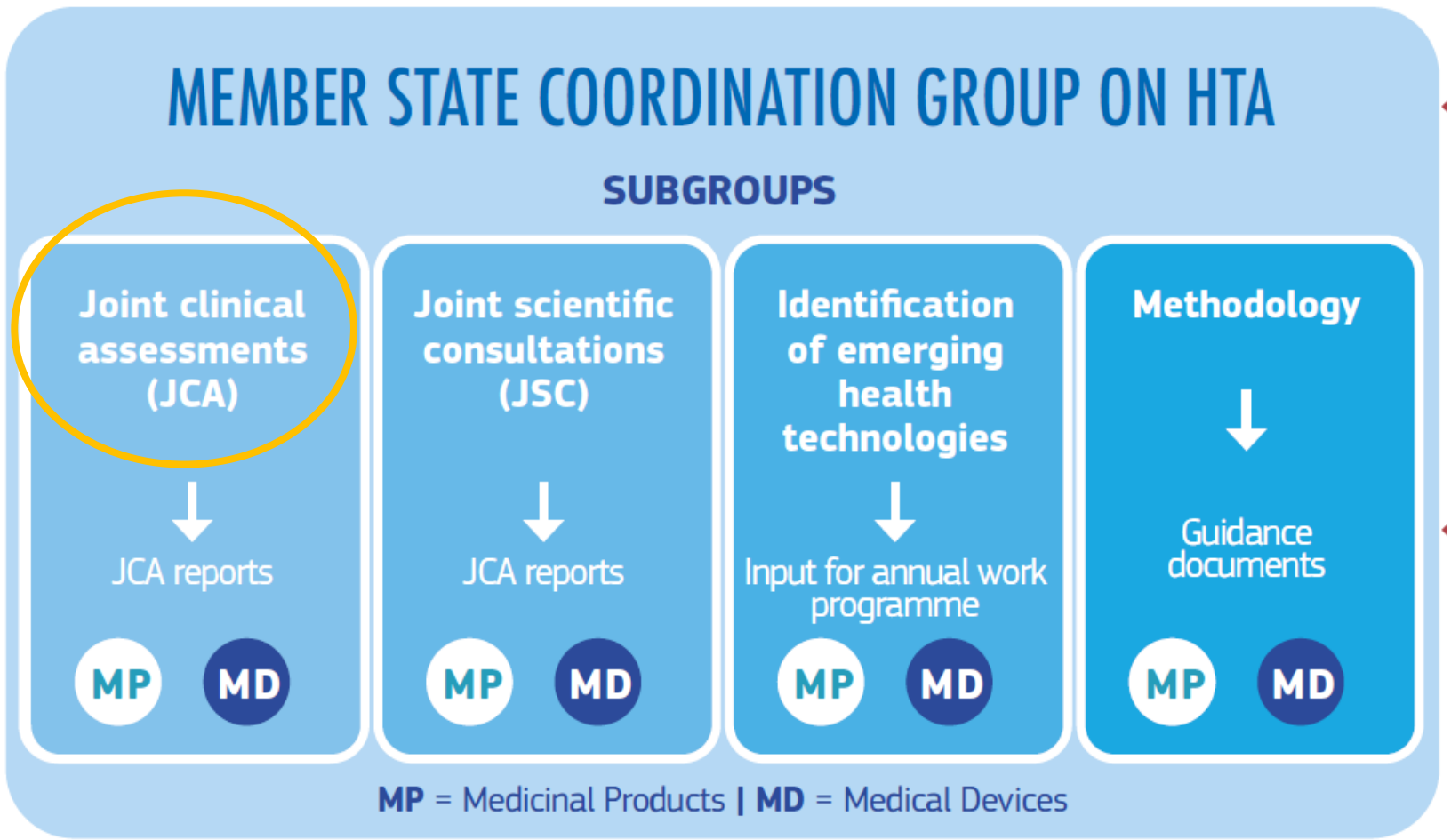
SG EHT

Britt Bekkers

SG EHT

CG: Coordination Group; Consortium = Brussels Centre for Collaboration in Health; SG EHT: Subgroup Emerging Health Technologies; SG JCA: Subgroup Joint Clinical Assessment; SG JSC: Subgroup Joint Scientific Consultation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2025

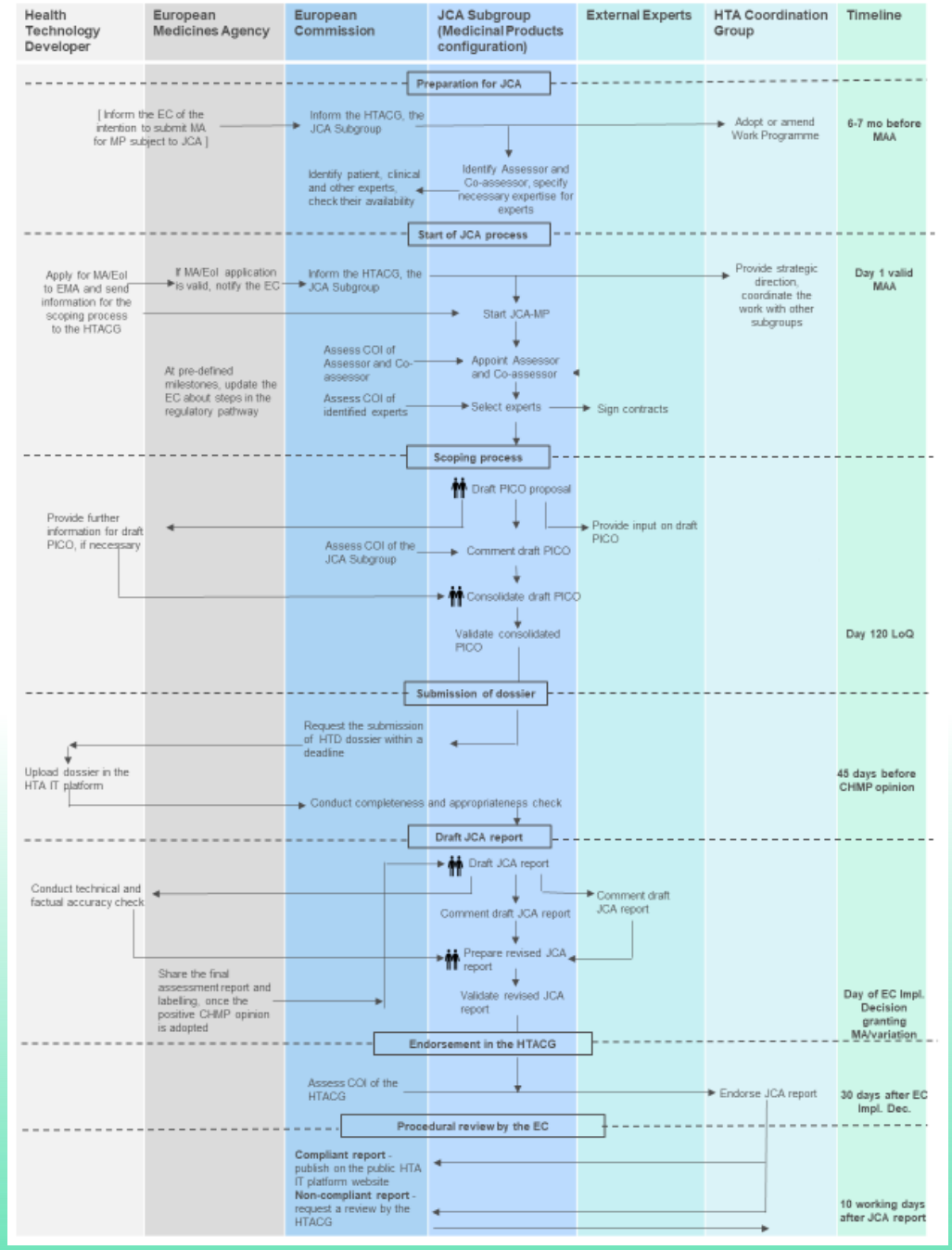
HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Medicinal products are subject to JCA according to the following timeline:

- from 12 January 2025 onwards: medicinal products for which the applicant declares that the application contains a new active substance for which the therapeutic indication is the treatment of cancer and medicinal products which are regulated as advanced therapy medicinal products (ATMP),
- from 13 January 2028 onwards: medicinal products which are designated orphan medicinal products,
- from 13 January 2030 onwards: the remaining medicinal products not previously included.

JOINT CLINICAL ASSESSMENT

IN PARALLEL WITH EMA



NATIONAL ASSESSMENT CTG-CRM

JCA process in parallel with EMA	
406 days	Standard procedure
277 days	Accelerated procedure

Scoping before submission dossier (JCA)	
P	Patient population
I	Intervention
C	Comparator
O	Outcome

Once the European report (JCA) is finished ….

2025 EUROPEAN HTA MEDICINES

What will be in the EU HTA-report ?

“description of the relative effects observed
for the health outcomes analysed,
Including numerical results and confidence intervals,
And an analysis of scientific uncertainty and
strengths and limitations of the evidence, e.g. internal and external validity.”

Once the European report (JCA) is finished ….

2025 EUROPEAN HTA MEDICINES

What's NOT in the EU report ?

"any value judgement,
ranking of health outcomes,
conclusions on overall benefit or
clinical added value,
any position on the target population
in which the medicine should be used,
or any position on
the place the medicine should have in
the therapeutic, diagnostic or
preventive strategy".

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2025 EUROPEAN HTA MEDICINES

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Reactions 2024

"It remains to be seen to what extent the individual HTA bodies take the JCA into account. In particular, it will be difficult to agree on what is the (appropriate) comparative therapy"

Health Policy and Technology 2024;13
Brinkhuis et al
European Access Academy's multistakeholder survey

Reactions 2024

"It remains to be seen to what extent the individual HTA bodies take the JCA into account. In particular, it will be difficult to agree on what is the (appropriate) comparative therapy"

"Still it is unclear, how member states will leverage/respect the JCA report. Additional local requirements may result in delays and bureaucracy [...]"

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Reactions 2024

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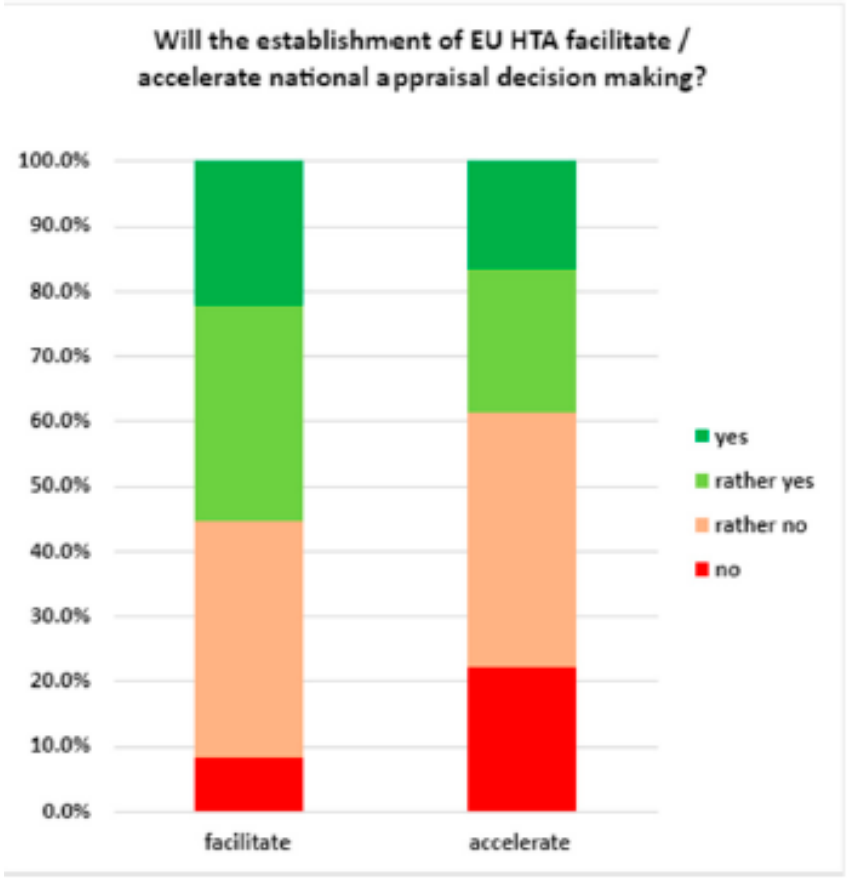
"Still it is unclear, how member states will leverage/respect the JCA report. Additional local requirements may result in delays and bureaucracy [...]"

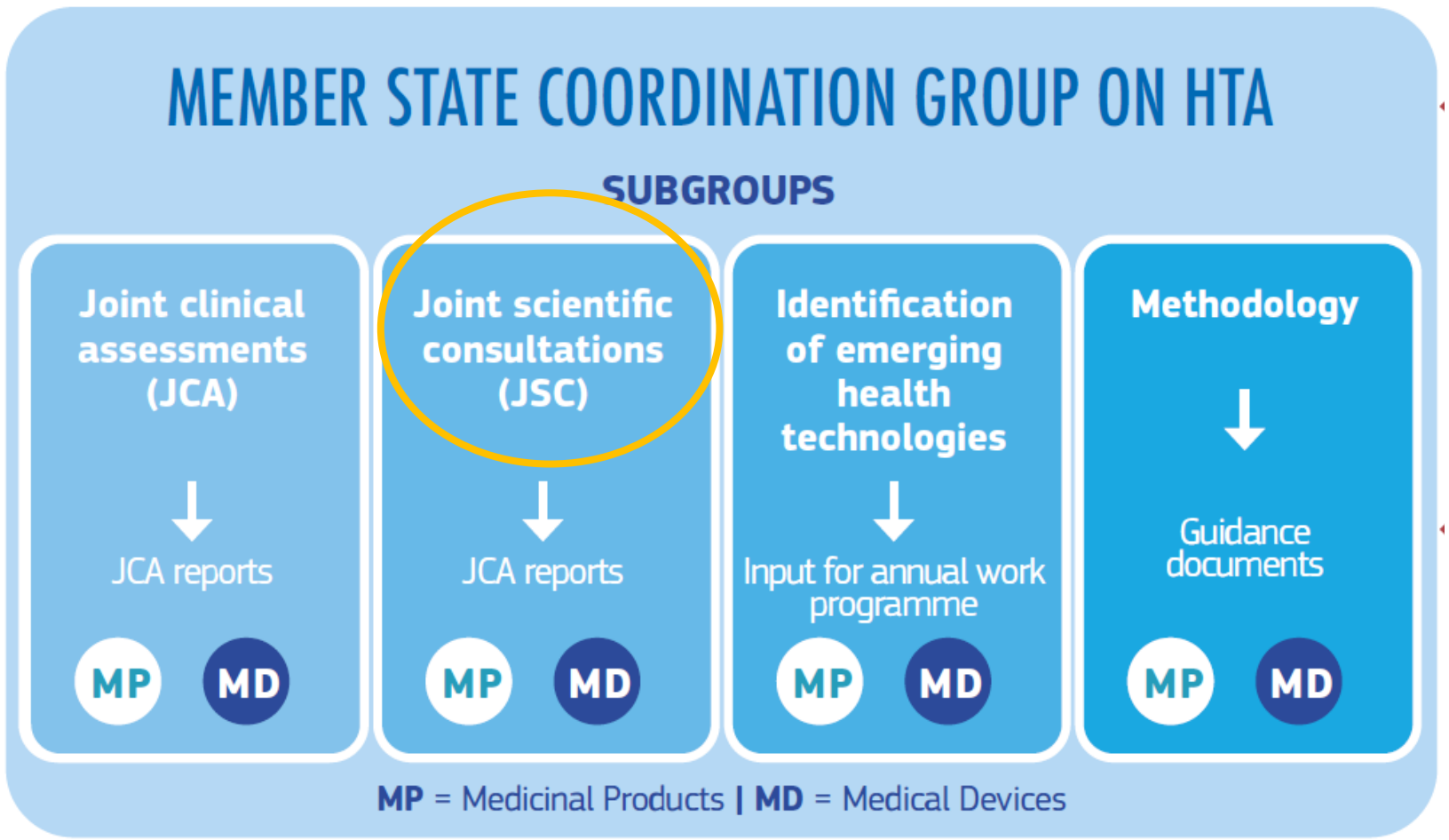
Timelines are also quite tight and require a well-organized team that know exactly what to do in each step".

Health Policy and Technology 2024;13
Brinkhuis et al
European Access Academy's multistakeholder survey

Reactions 2025



Journal of Market Access and Health Policy
Julian et al
European Access Academy's multistakeholder survey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Joint Scientific Consultations

British Journal of Clinical Pharmacology

The impact of parallel regulatory–health technology assessment scientific advice on clinical development. Assessing the uptake of regulatory and health technology assessment recommendations

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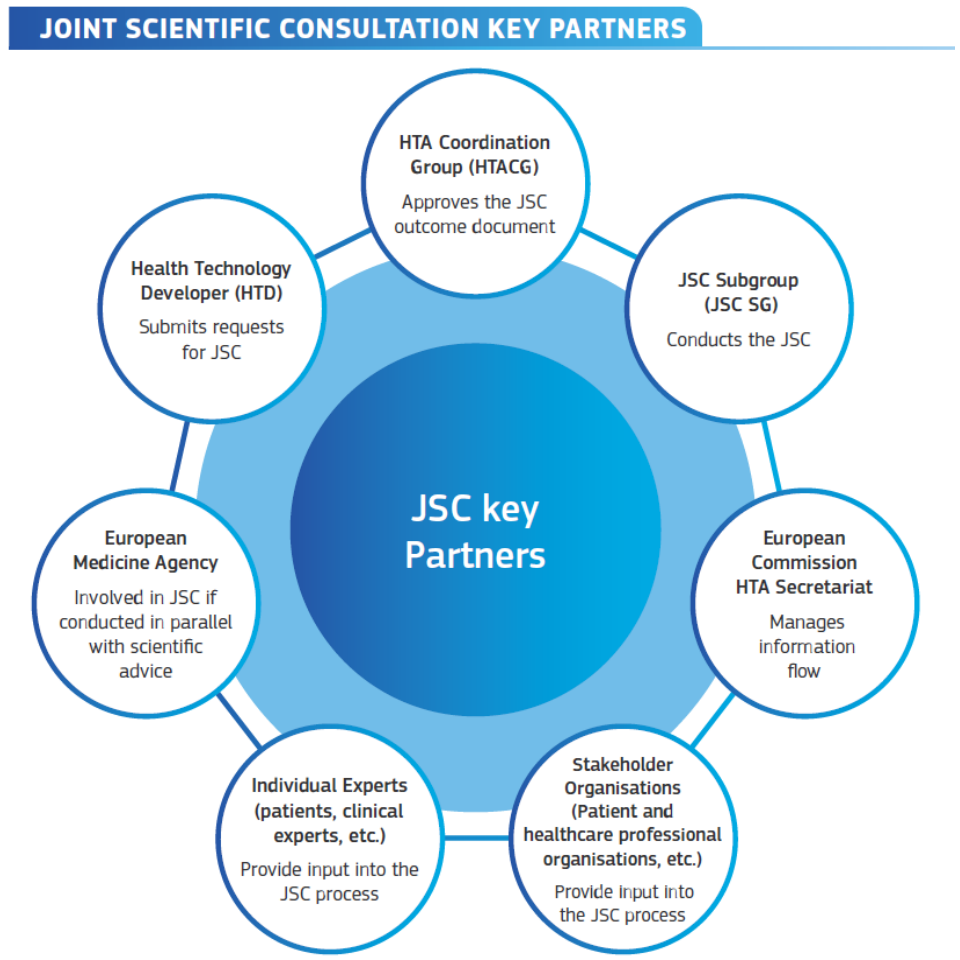
Joint Scientific Consultations, from 2025 on

Before phase III study

3 periods/year

Joint HTA advice ± EMA CHMP scientific advice

JSC process 70 days + amended briefing pack 30 days



Conclusion

- Joint HTA has started
- Long history track
- Shift from national assessment -> crossborder assessment
- Competent Pricing and Reimbursement authorities remain national