10 February 2025

POSITION PAPER ON THE CHALLENGES WITH THE JOINT CLINICAL ASSESSMENT (JCA)

List of Editors

Krzysztof Łanda	Watch Health Care Foundation, HTA Formedis, Warsaw, Poland	kl@krislanda.eu
Lieven Annemans	Faculty of Medicine & Health Science, Department of Public Health, De Pintelaan 185, Blok A-2 Verd, Belgium.	Lieven.Annemans@Ugent.be
Mark Parker	ZEM Solutions d.o.o., Belgrade, Serbia	mark@zem-solutions.com

List of contributing authors

Gérard De Pouvourville	ESSEC Business School and Research Director of the National Centre for Scientific Research, Paris, France	b00072308@essec.edu
Maarten Postma	Department of Health Sciences, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands; Department of Economics, Econometrics & Finance, University of Groningen, Faculty of Economics & Business, Groningen, the Netherlands; Department of Pharmacology & Therapy, Universitas Airlangga, Surabaya, Indonesia; Center of Excellence in Higher Education for Pharmaceutical Care Innovation, Universitas Padjadjaran, Bandung, Indonesia.	m.j.postma@rug.nl
Michael Schlander	Division of Health Economics, German Cancer Research Center (DKFZ), Heidelberg, Germany; Mannheim Medical Faculty, University of Heidelberg, Mannheim, Germany; Alfred Weber Institute (AWI), University of Heidelberg, Mannheim, Germany; Institute for Innovation & Valuation (InnoVal(HC)), Wiesbaden, Germany	m.schlander@dkfz-heidelberg.de
Nick Verhaeghe	Department of Public Health, Interuniversity Centre for Health Economics Research (I-CHER), Ghent University, Ghent, Belgium; Department of Public Health, Interuniversity Centre for Health Economics Research (I-CHER), Vrije Universiteit Brussel, Brussels, Belgium	Nick.Verhaeghe@ugent.be

Oriol Solà-Morales	Fundació HiTT, Barcelona, Spain	osola@hittbcn.com
Tanja Novakovic	ZEM Solutions d.o.o., Belgrade, Serbia	tanja@zem-solutions.com
Tomáš Doležal	VALUE OUTCOMES s.r.o., Prague, The Czech Republic	dolezal@iheta.org
Ulf Persson	The Swedish Institute for Health Economics, IHE, Lund, Sweden	ulf.persson@ihe.se
Vanesa Benkovic	University of Zagreb School of Medicine, Andrija Štampar School of Public Health, Zagreb, Croatia; Novo Nordisk Hrvatska, Zagreb, Croatia	vanesa.benkovic@farmakoekonomika.hr

Introduction

Health Technology Assessment (HTA) has become a key tool in modern healthcare, supporting evidence-based policy decisions by evaluating medical, economic, legal, patient and social aspects, and ethical implications of new technologies. Historically, HTA emerged from the need to address the rapid growth in healthcare technologies on the one hand and the rise in costs on the other hand. HTA aims to provide decision makers with the evidence they need to ensure their decisions will improve the effectiveness and efficiency of healthcare.

The Joint Clinical Assessment (JCA) framework[1] was developed to standardize the evaluation of health technologies across EU member states. Its goal is to reduce duplication in assessments and accelerate the adoption of new technologies. The idea behind this design is to ensure a consistent approach to assessing clinical efficacy and potential effectiveness, allowing for rapid dissemination of beneficial treatments across the union. Within EU's HTA Framework[2], JCA is an integral part of the EU strategy to streamline the evaluation of new health technologies across member states.

To better understand the organizational framework of JCA, we will shortly guide the reader through the process which begins with the scoping phase, a clearly defined assessment of specific aspects of the health technology to be analysed. This includes identifying the relevant target populations, settings, all relevant comparators and predefined clinical outcomes. The following phase is evidence submission. This evidence must be substantial and rigorous enough to withstand the scrutiny of the subsequent stages of assessment.

At the heart of the JCA is the assessment phase, structured around the PICO framework (abbreviation for: Population, Intervention, Comparator, Outcome). This involves a detailed analysis of the population that will benefit from or be affected by the technology, specifying the proposed new intervention itself, identification of comparator(s), which involves identifying the current standard of care or other interventions against which the new technology will be evaluated, and finally, the outcome, which focuses on determining the efficacy and potential effectiveness of the intervention in the context of the subpopulations suitable for the intervention.

[1]https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

[2] https://www.eunethta.eu/

Post-assessment, the process moves into review and consultation. Here, a draft report generated from the assessment phase is subjected to analysis by independent experts and may also be opened to public consultation. This stage allows for a diverse range of stakeholders to offer insights, critique, and suggestions, ensuring a robust and inclusive review process. The culmination of this rigorous journey is the final reporting phase. This phase involves synthesizing all feedback to prepare a comprehensive report that outlines the findings related to the efficacy and potential effectiveness of the technology.

Finally, the JCA finishes into implementation advice. Although the JCA strictly focuses on the clinical aspects without making value judgments about the technologies, the insights derived from the process are used to support decisions on whether and how the assessed technology should be integrated into healthcare systems.

To facilitate a better understanding of the process before going into key points of critique, we are showing the JCA process scheme in Figure 1.

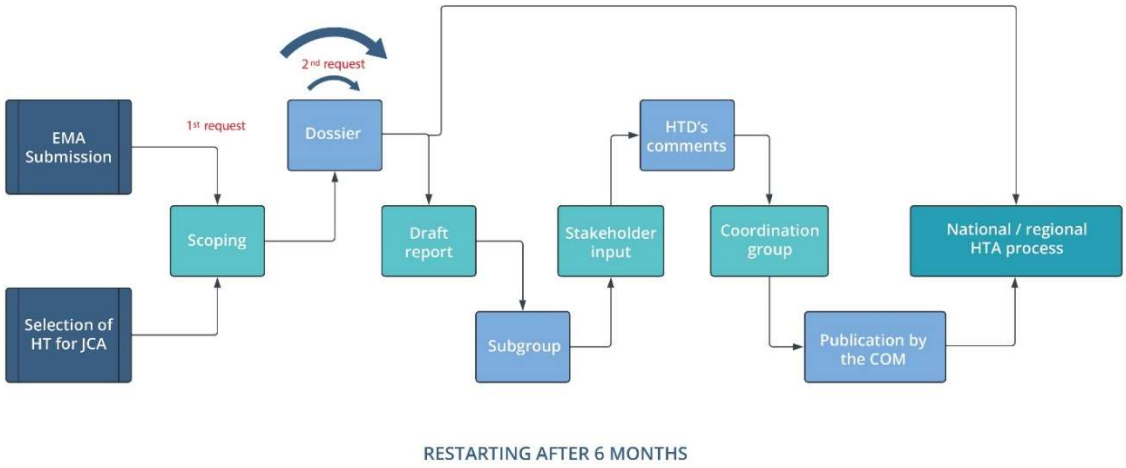

Figure 1. JCA process

Abbreviations: COM – European Commission; HTD - Health Technology Developer, HT – Health Technology

Note: The Coordination Group shall carry out JCAs on health technologies on the basis of its annual work programme. The Coordination Group initiates JCA of health technology by designating the subgroup to oversee the conduct of the JCA on behalf of the Coordination Group. The Coordination Group is selecting HTs for JCA and calls the health technology developer to submit a dossier. COM informs the HTD of the assessment scope and requests the submission of the dossier (first request).

The dossier is prepared by HTD. Complete dossiers are subject to assessment. The assessors will conduct the clinical assessment, prepare a draft report, and consult relevant stakeholders. The draft report is then shared within the JCA subgroup for review. Subsequently, the revised draft report is shared with the health technology developer for comments, albeit only purely technical or factual inaccuracies can be pointed out at this stage. Then the revised draft report is shared with the coordination group. The Coordination Group endorses reports and summary reports by consensus.

This critique of the JCA process and content within the EU's HTA framework aims to illuminate the complexities of creating a standardized yet adaptable approach to health technology assessments.

The paper will explore the balance between EU-wide harmonization and the need for assessments that reflect local health contexts. By analysing current methodologies and their implementation challenges, the paper seeks to propose actionable improvements, enhancing the efficiency and impact of HTA and JCA across the European Union.

Critique of the JCA process

The JCA process, despite its structured approach, presents numerous challenges that can impact its effectiveness and efficiency. In this part, the authors want to go deeper into specific critiques of the JCA process, highlighting areas where room for improvements were identified.

Evidence generation in health care is a highly complex and expensive activity which has defined the revolution in healthcare over recent decades. HTA has emerged as the key mechanism to summarize the available evidence in a form that is useful for decision making. The process of collecting and condensing this evidence can be described under the range of light to heavy touch HTA. Under light HTA all the responsibilities are borne by the HTD, under heavy HTA all the responsibilities are borne by public health authorities. These responsibilities can include additional evidence generation required for informed decision making. Light HTA has also been described as the process of taking third party HTA reports.[3] In reality, many HTA agencies take a mixed model approach, applying shared responsibilities for different aspects of assessment and appraisal.

Feasibility and efficiency

The practicality of conducting JCAs under the current model is questioned, particularly regarding the allocation of public resources. The authors argue that the process is neither efficient nor cost-effective, given the anticipated low impact of JCA on reimbursement decisions and restricted uptake of innovations evaluated through this system. The critique extends to the operational model which does not address the fundamental problems associated with the responsibility for evidence generation within the highly diverse health care systems inside the EU.

Under the current model there are two sources for HTA materials to become available under the JCA. Either a draft report is created by JCA assessors (heavy touch, Figure 1) or if a member state conducts its own HTA assessment it is obliged to make the report available to other member states via the JCA platform.

"*Where an HTA, or its update, is carried out by a Member State on a health technology referred to in Article 7(1), that Member State, through its designated member in the Coordination Group, shall provide the national assessment report on that health technology to the Coordination Group through the IT platform referred to in Article 30 within 30 days after its completion.*"[4]

However, the applicability of such HTA reports outside of their own economic context is likely to be severely limited, subject to confidential information and value judgments, limiting their usefulness for decision making.

[3] https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/blueprint-for-health-technology-assessment-capacity-building-lessons-learned-from-malta/C0763BABB7C0266B2BAC1C7074E78D6F

[4] REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 Article 24 National clinical assessment reports

Responsibility of the quality of the submitted reimbursement dossier

Another critical issue that needs to be considered concerning the introduction of JCA is the responsibility for producing JCA reports. In systems with a light-touch HTA agency, the manufacturer is responsible for the quality of the submitted reimbursement dossier. In case of errors in the submission, incomplete submission or use of inappropriate methods, the reimbursement application can be rejected or delayed until it is of sufficient quality for use in decision making. The Market authorization holder (MAH) is entirely bearing the consequences of low-quality HTA submissions. On the contrary, heavy-touch HTA agencies are fully responsible for the analyses they undertake. In the heavy-touch model, HTA agencies need to be prepared to defend the methods used and approaches utilized in their analyses, this will result in many substantial complications for decision making in European institutions.

Prioritization and transparency

The prioritization process within the JCA framework is seen as vulnerable to inefficiencies and potential bias. Limited resources force prioritization of topics, which can be subject to political influence, reducing the transparency and fairness of the JCA process. This section argues for a restructuring of how priorities are set to mitigate these risks. Prioritization in a light-touch approach is not needed at all as any light-touch HTA agency operates due to “first in – first out” principle – they stand for quality check of full HTA dossiers required by law and prepared by MAHs, so today’s application will be evaluated earlier than tomorrow’s one.

Operational constraints and resource allocation

The process for approving JCA reports, including the timely execution by the Coordination Group (no later than 30 days following the adoption of the Committee for Medicinal Products for Human Use (CHMP) decision granting a marketing authorisation), faces significant logistical challenges. Detailed timelines for various JCA process steps remain undefined, which complicates the planning and allocation of necessary resources. Moreover, the ability of member states to conduct national updates of assessments creates an additional layer of complexity and potential inconsistencies.

Integration with national HTA processes

HTA by national bodies across both Europe and globally, must address two distinct types of decision problems. The first – Single Technology Assessment (STA), limits the scope of assessment to a single technology and the patient population who could specifically benefit from this technology. The second – Multiple Technology Assessment, assesses all the potential treatment options, available within a broad disease category, potentially redefining the entire treatment pathway. STAs, while more numerous than MTAs, are well understood, with all the necessary clinical evidence already collected by the technology developer. MTAs however, are often only conducted by heavy touch agencies such as NICE in the UK, due to the requirement to collect additional evidence for existing and competing technologies already available on the market. For example, national diet and exercise programmes verses new weight loss medications, or the broad range of services for cystic fibrosis.

Despite the EU-level design of the JCA, it necessarily operates separately from national value judgments, particularly regarding the medical added benefit. Indeed, JCA is only descriptive and absent of any appraisal. This separation can lead to JCA reports that lack the necessary depth in

evidence required for national decision making, leaving appraisal of health technologies to individual countries, inevitably leading to discrepancies in health technology coverage across the EU.

Member States will also be faced with the same challenges that existed before the introduction of JCA, particularly with respect to the selection of comparators and the integration of new clinical evidence into their existing healthcare systems. This leads to discrepancies between the intended operation of the JCA and its practical implementation.

Stakeholder engagement, systematically involving patients, healthcare professionals, and payers from all member states in the HTA process is a vital part of transparent decision making. It is a requirement for a reports relevance and acceptance of HTA outcomes across different regions, and contribute to more informed decision-making. Although included in the process, it is unclear how much opportunity stakeholders will have to contribute to JCA reports.

Limitations of Joint Scientific Consulations (JSC)

There is a very limited number of products which will be covered by Joint Scientific Consultation (JSC) in the coming years due to limited resources dedicated to this task. It can be expected that only a very limited number of companies will be able to benefit from JSCs. Products are selected for JSC based on a set of broad criteria. The ongoing concern is that slots for joint advice will be very limited, meaning some companies may miss out – which creates a high risk of inequality and a lack of transparency.

Timeliness of JCAs

Time for systematic review

Reimbursement decisions need to be taken based on up-to-date evidence. The timeliness of submitted evidence and conducted assessments is paramount to every decision-maker. JCA will be conducted at the time of the regulatory decision for that product. Nevertheless, follow-up local HTA procedures will not be initiated until the local HTA body or health technology developer (depending on the local HTA agency's model) develops the country-specific parts of HTA. Substantial differences between countries are expected regarding the timing of market access endeavours. Thus, for some countries, JCA reports can easily become outdated and not useful for the coverage decision-making process. This does not necessarily apply to clinical evaluation of an innovative drug or medical device as marketing authorisation is going to be based usually on a single phase III or phase II trial, but that will certainly apply to clinical evaluation of comparators and the evolving nature of evidence across disease areas. Comparators include both drugs or procedures of well-established use, in addition to newer technologies. Differences in the availability of technologies and clinical experience between countries can have significant impact on the local value of technologies. Basing efficacy analysis on up-to-date systematic review is also a value judgement that differs between countries.

Time between JCA and cost effectiveness/budget impact analysis

JCA is prevailingly designed in a heavy-touch approach, meaning that thorough and detailed clinical assessments will be performed by public employees, so using public resources. In a majority of countries economic evaluation and budget impact analysis (BIA) play key roles in appraisals of health technologies and decision making for pricing and reimbursement. Even if there's an intention to expedite reimbursement submissions across all EU member states following a JCA — especially since duplicating clinical analysis efforts is prohibited—and assuming no delays from the Marketing

Authorization Holders (MAHs), it's important to recognize that there's still a significant time lapse from when JCA results are available to when economic evaluations (such as cost-effectiveness and cost-utility analyses) and BIAs are prepared. In the meantime, many clinical assessments will become outdated. This might be suitable for marketing authorisation, but it is certainly not enough for decision-taking on pricing and reimbursement. This factor alone will result in JCA not being an important factor in reimbursement policies, and it's expected that MAHs will continue to prepare comprehensive and up-to-date HTA reports as is currently standard practice in much of Europe.

Updates Over Time

Although the EU-HTA regulation[5] envisages a procedure for updating JCA reports, it is yet to be seen how efficient this process will be. In a heavy-touch approach it is expected to be very costly and likely inefficient (while compared to the performance of the Cochrane Collaboration). Each JCA report might require multiple updates as the available evidence pool grows rapidly. In 2022, the EMA granted marketing authorisation to 89 new medicines.[6] As declared, ultimately all products approved centrally will be assessed as part of the JCA procedure. It is easy to predict that keeping all JCA reports up-to-date and ready for local reimbursement processes will be extremely tedious. Updating a JCA report at the European level can even prolong the entire coverage decision-making process. Local updates might be seen as a more straightforward way of proceeding. Still, the issue of work duplication (local agencies duplicating work already done at the European level) becomes problematic.

Many of these challenges could be overcome by establishing regional HTA collaborations that cluster countries with similar healthcare systems and economic statuses. These regional HTAs can share resources and insights while still tailoring their appraisals to regional specifics, reducing the workload and improving the applicability of HTA outcomes.

Ultimately, the ambition to reduce duplication of work across national HTAs by centralizing assessments through the JCA is at the end of the day a clear paradox. The fundamental processes intended to minimize repetitive evaluations, may overlook the fine details of value judgments required at the national level, leading to potential inefficiencies and contradictions within the system.

Critique of the JCA content

Operational Challenges and Value Discrepancies

As mentioned previously, the JCA is designed to operate independently from the value judgments central to national HTA processes, particularly concerning the medical added benefit, which remains a national prerogative. According to the EU-HTA regulation (Article 9(1)), JCA reports are expressly forbidden from making value judgments or drawing conclusions on the overall clinical added value of the assessed technologies. They are restricted to a descriptive analysis of scientific evidence, including the relative effects of health technologies and the certainty of these effects, which is shaped significantly by the strength and limitations of the available evidence.

While this design theoretically maintains a clear distinction between clinical assessment and value determination, it does create a dichotomy where JCA outputs are not binding and thus do not

[5]EUR-Lex - 32021R2282 - EN - EUR-Lex. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282#d1e1112-1-1 (accessed Mar. 10, 2023).

[6] Medicine evaluation figures | European Medicines Agency. https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures (accessed Mar. 12, 2023).

mandate specific health coverage decisions at the national level. Consequently, the appraisal of health technologies, which includes judgments about their value and utility, remains the sole province of individual EU member states. The added value of JCA in this regard is very unclear.

Challenge on JCA's Approach to Value Judgments

Handling of value judgments, which are inherently complex and varied across different national contexts presents important challenges. The core issue lies in the attempt to standardize health technology assessments across the EU, again, without imposing value judgments, which traditionally vary significantly between countries due to differences in scores of health-related Quality of Life (QoL) measures and generally the use of Quality-Adjusted Life Years (QALYs) in economic evaluations. Not to mention different ways of health care financing and organization which define how value is attributed. These discrepancies often lead to a misalignment in how value is perceived across borders, limiting the value of shared HTA reports from individual member states under the JCA platform.

Systematic reviews and updating challenges

One of the fundamental criticisms of JCA reports is their apparent inability to handle full-scope systematic reviews which include all relevant comparators, and is mandatory by law in some member states. This limitation can lead to JCA reports quickly becoming outdated, potentially rendering them irrelevant for decision-making on coverage. The European Commission is unlikely to allocate sufficient resources to conduct the planned JCAs promptly, raising concerns about the efficiency of updating these systematic reviews.

MAHs are not obliged to submit evidence collected in the form of systematic reviews on all relevant comparators.[7] It is possible that technology developers will submit such systematically collected and up-to-date evidence also for comparators, but the costs of such reviews and then necessary frequent updates are going to be substantial.

There is nothing within the JCA framework to allocate specific responsibility for the wider evidence collection necessary for informed national decision making, even if limited to clinical aspects only.

Extra evidence and patient (market) access delay

Local HTA bodies will still be able to request additional evidence from health technology developers, for example, in a case when JCA reports do not align with the value drivers of a particular HTA agency or national P&R legal criteria.

It remains to be seen whether the stepwise approach (JCA at EU level, consideration of specific evidence at member state level), will accelerate rather than delay market access of new medicines. This refers to the extent and nature of evidence mandated by the central JCA vs the amount of evidence that is required by individual member states. In other words, a rather lean and potentially consensus-orientated, “one-size-fits-all” JCA process might inspire generation of additional evidence at the member state level with negative effects on market access timeliness and efforts needed by companies to assemble all necessary evidence at the EU level.

[7] It is still unclear. Some representatives of HTA agencies in EU claim that preparation of systematic reviews for the innovative drug and its comparators will be imposed on MAHs and that MAH will bear the costs of full comparative clinical evaluation. No provisions directly pointing it out were found.

One of the overarching aims of JCA is to accelerate patient access to innovative drugs. According to the European Federation of Pharmaceutical Industries and Associations' report[8], huge inequalities in time to patient access to innovative oncological treatments exist within Europe. It seems questionable if planned JCA can help with these inequalities, considering that most countries with limited access also suffer from small and inefficient HTA capacities. Paradoxically JCA could even deepen the two/three speed Europe from the innovative medicines access perspective.

In several European countries patients will not receive access to new innovative pharmaceuticals without an assessment of the value and a subsequent price and reimbursement decision. This value assessment is based on the clinical evidence from RCTs, often short-term placebo-controlled trials or head-to-head trials. Outcomes in RCTs are often surrogate endpoints and not the patient-oriented endpoints that are required for the value assessment. A value assessment often necessitates additional clinical evidence to link the surrogate endpoints in the RCTs to demonstrate value[9]. However, It is unlikely that this additional clinical evidence - generalised, preference based estimates of clinical benefit - will be included in the JCA reports. For countries that use cost-effectiveness modelling for demonstrating the value of a new treatment, this information is a fundamental component of decision making. If a JCA will be prepared without this additional clinical evidence, data and information, there is risk that the uptake of a new drug will be significantly delayed. Today, both these two kinds of clinical evidence, i.e. short-term RCT and supplementary clinical cohort data, are demanded in HTA procedures relying on economic modelling approaches. Both types of clinical evidence are costly to generate and depend wholly on the national healthcare context.

Differences in Standard of Care

The selection of appropriate comparators is one of the most critical challenges. There are significant complexities related to differing national and local clinical pathways in the process of clinical assessment across the EU. According to most guidelines on health economic evaluation, the comparators in a health technology assessment should be those most likely to be replaced. The number of comparators will therefore vary meaningfully depending on the product and indication in question.

Value depends on the available comparators, the patients' characteristics and on how health care provision is organised. This differs significantly from the clinical evidence collected in RCTs, which are designed to demonstrate high internal validity, under strict clinical conditions and monitoring which do not align with any real world clinical practice. In several countries external validity, i.e. how a medical technology is expected to work in real life, is important for the price and reimbursement decision, in particular in those countries that apply cost-effectiveness in the reimbursement decision making. External validity often needs real world data that can demonstrate the importance of patients' behaviour for adherence, prescribers' behaviour and the ability to classify patients degree of severity. Outcomes may also be defined differently in RCTs versus real world health care. Examples for such differences include the definition of disease progression in oncology, evolving evidence for treatment

[8] Vintura, "Every Day Counts: Improving Time to Patient Access to Innovative Oncology Therapies in Europe," 2020. [Online]. Available at https://www.efpia.eu/publications/downloads/efpia/every-day-counts-improving-time-to-patient-access-to-innovative-oncology-therapies-in-europe/nerally need

[9] https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-022-01830-3 In search of a 'pan-European value set'; application for EQ-5D-3L

targets such as those in diabetes, or new definitions of entire patient populations such as NASH or some chronic migraine patients being reclassified as medication overuse headache. There are also differences in effectiveness when compliance is imperfect. Often compliance differs between RCTs and the real world, with such differences contributing significantly to the value of a technology. There are significant differences very well described in the literature, for example diabetes treatment and schizophrenia treatments, when short and long acting compounds are compared and people change their behaviour.

Conclusion on JCA challenges

The proposed changes to European HTA, namely the way that JCA is going to be introduced, form a sword with two edges. We argue that it will most likely bring minimal benefits (if any), and might also create potential threats to all stakeholders. Disjunction of JCA from final decision-taking poses a number of challenges which cannot be easily addressed. The main hope associated with the introduction of JCA is the reduction of work duplication and accelerated patient access to innovative treatments, which will most likely not be realized. The main hope might actually manifest opposite outcomes - more work and delayed patient (market) access. Pressure from patient advocacy groups seeking rapid access to drugs approved and clinically assessed as part of JCA might be much more significant to decision-makers and politicians than to MAHs.

It is hardly believed that JCA in its current format will allow for full scope systematic review for all relevant comparators. Moreover, JCA reports will quickly become outdated and invalid for decision-making on coverage. It is uncertain if the European Commission will dedicate enough resources to conduct all planned JCA promptly.

Operating JCA in a heavy-touch HTA model is likely to become a source of inefficiencies. Public resources spent on JCA should rather benefit patients across Europe when alternative systemic measures are introduced. Such measures of an alternative joint HTA model are presented in the expert opinion on the Pan-European Solidarity Reimbursement List (PANSOL)[10]. With PANSOL clear benefits of efficiency, equity and cost reduction could be achieved, but there are also challenges around implementation complexity, variability of health needs and also question of sovereignty of member states giving control over their own drug pricing and reimbursement decisions to a centralized EU body.

The varying healthcare financing and organizational structures across the EU further complicate the universal applicability of a centralized HTA model like JCA.

As we look toward to the future, it is essential to address these and many other, unanswered questions and challenges to ensure that any reform in European HTA, including the adoption of JCA, genuinely contributes to better care for patients and the efficient utilization of healthcare resources. Engaging a broad range of stakeholders, including patients, healthcare professionals, and policymakers, in the reform process will be crucial to enhancing the relevance and acceptance of HTA outcomes.

Ultimately, if the European Commission is to realize the full potential of JCA, a significant modification in the operational and strategic framework may be necessary. This means that a potential re-

[10] The follow-up publication explaining the PANSOL proposition should be expected shortly.

evaluation of the heavy-touch model and finding ways of integrating up-to-date clinical evidence to keep pace with rapid medical innovations is a must. Only with these (demanding) adaptations can the JCA initiative hope to fulfil its promise of reducing work duplication and truly accelerating patient access to new treatments in EU.

The staged approach to develop JCA, starting in oncology before expanding the regulations to a wider range of disease areas will provide a vital time period to address these concerns.

Summary of key concerns:

JCA process

- The current "heavy touch" model of JCA process is neither efficient nor cost-effective (performed by public employees, using public resources).
- A "heavy touch" agency is fully responsible for producing JCA reports (the methods used, and approaches utilized in their analyses requires significant transparency).
- Limited resources force prioritization of topics, which can be subject to political influence, reducing the transparency and fairness of the JCA process.
- Detailed timelines for various JCA process steps remain undefined, which complicates the planning and allocation of necessary resources
- It is unclear how much opportunity all stakeholders will have to contribute to JCA reports.

Timelines

- JCA reports can easily become outdated and therefore not useful for a coverage decision making process.
- Any significant time lapse between JCA results becoming available for national economic evaluations (such as cost-effectiveness and cost-utility analyses) and BIAs are prepared is likely to result in duplicated effort.
- The EU-HTA regulation envisages a procedure for updating JCA reports, in a heavy-touch approach it is expected to be costly and likely inefficient.
- The issue of work duplication (local agencies duplicating work already done at the European level) is insufficiently addressed, in practice most clinical evidence is already provided by MAHs, it is unclear what work can be further centralised, vs the valuation of a decision problem in a local context, which legally JCA must avoid.
- The fundamental processes intended to minimize repetitive evaluations, may overlook the finer details of value judgments required at the national level, leading to potential inefficiencies and contradictions within the system.

JCA Content

- JCA must operate independently from value judgments central to national HTA processes, particularly concerning the local economic benefit, which remains a national prerogative.
- JCA outputs are not binding and thus do not mandate specific health coverage decisions at the national level.

- Handling of value judgments, which are inherently complex and varied across different national contexts presents important challenge.
- While the preference for biomarkers and surrogate endpoints necessary to quantify the value of technologies in a local context varies between member states, such evidence generation presents a significant opportunity to reduce duplicated local work. However, JCA does not explicitly include any mechanism to harmonise this evidence across the EU.
- It is unclear who is responsible for collecting and resourcing the clinical evidence needed for comparators.
- JCA reports in their currently proposed format cannot handle full-scope systematic reviews which include all relevant comparators.
- Systematic reviews for decision-making purposes on pricing and reimbursement must be up to date, any JCA report therefore has a limited useful lifespan with no clear mechanism defined as to when and how they should be updated.
- Requiring member states national HTA reports be made available at the EU level is subject to significant confidentiality and copyright issues which have not been addressed.
