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Health technology assessment in Europe: A comparison of organizations and introduction to the European regulation

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ABSTRACT

Health Technology Assessment (HTA) is a multidisciplinary process that evaluates the medical, social, economic, legal, and ethical aspects of health technologies to determine their value throughout their lifecycle. With rising healthcare costs in Europe, robust HTA processes are crucial for making informed decisions that promote an equitable and efficient health system. HTA practices date back to 1967 in France and have expanded across Europe, with most countries adopting HTA models to guide pricing and reimbursement decisions. An analysis of European Health Technology Assessment bodies (HTAb) was conducted through an online survey to showcase the diversity of HTA systems while highlighting their shared goals. The survey, sent to 33 HTAb from July 8 to August 25, 2024, included 11 multiple-choice questions about their organization and processes, allowing for optional free text responses. Data collected were self-reported and analysed using descriptive statistics, with minimal verification of responses. Despite some differences in remit and scope, European HTAb remain steadfast in their resolve to collaborate. The European Commission and EU member states have fostered collaboration among HTA bodies through initiatives like EUnetHTA, culminating in the adoption of the HTA Regulation (EU) 2021/2282, which will be implemented starting January 12, 2025 with the production on joint clinical assessment and joint scientific consultation for some medicinal products and high-risk medical devices. The HTAR offers numerous opportunities for collaboration. Joint productions will foster a culture of mutual learning, allowing countries to benefit from shared expertise and data while ensuring the rigorous and transparent assessment of new health technologies. Moreover, a more unified approach to HTA could accelerate the adoption of new and effective technologies at the continental level, ultimately improving patient outcomes across Europe.

1. Introduction

Health technology assessment (HTA) is a multidisciplinary process that summarizes relevant information about medical, patient, social, economic, legal or ethical issues and that is used to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system in a systematic, transparent, unbiased and robust manner [1,2]. As healthcare and health products costs continue to rise across Europe [3–6], the importance of robust HTA processes cannot be overstated. HTA methods are used to assess a wide range of health technologies and interventions: medicinal products (MP), medical devices (MD), digital MD, other health technologies that are neither MP nor MD (such as foodstuffs intended for special medical purposes), vaccines, public health programs, and diagnostic and therapeutic procedures.

Practice of HTA can be found in France as early as 1967 with the creation of a committee responsible for recommending MP for inclusion or removal from the list of drugs reimbursed by French social security organizations [7]. In 1980, the committee was renamed the Transparency Committee (*Commission de la Transparence*) which, since 2004, has been housed at the French National Authority for Health (*Haute Autorité de santé*, HAS) [8]. HTA's foothold in Europe was strengthened, notably in Sweden with the creation of the Council on Technology Assessment in Healthcare (SBU) in 1987, and the establishment of the National Institute for Clinical Excellence (NICE) in the UK in 1999 [9,10].

Today, most European countries have implemented an HTA model to support their national decisions on pricing and reimbursement of health technologies as well as diagnostic and therapeutic procedures or public health interventions [11]. However, the HTA landscape in Europe is characterized by significant diversity, particularly in terms of organizational structure, coverage (national or regional), and scope of the technologies assessed [12,13].

In general, Northern European countries have a decision-making model based on health economics. This means that, to be reimbursed,

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products must be cost-effective, and the cost per quality-adjusted life year (QALY) must remain below a certain threshold. However, this value may not be strictly defined and/or may vary depending on medical need or disease prevalence. This evaluation system mostly developed by NICE, the HTA organisation in charge of the regulation in England and Wales, is now used as a reference in all the United Kingdom countries, Ireland, Netherland, Belgium as well as Scandinavian countries [14].

In contrast, many Southern European countries and Germany follow a decision-making model closer to the French one, where clinical effectiveness is the primary criterion for determining whether a new product should be reimbursed. Health economics can then play an additional role in price negotiations. In countries like Spain [15,16] and Italy [17], regional authorities can also influence access decisions, while Germany's HTA process is the most aligned with the French model. In both France and Germany, the added value of a new product is assessed on a well-defined scale, and the outcome of this evaluation directly impacts pricing decisions.

Unlike France, however, Germany has two agencies involved in the HTA process. The Gemeinsamer Bundesausschuss (G-BA) is the authority responsible for making formal decisions regarding the additional benefit of medicinal products. However, it can first commission the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), an independent foundation, to assess the evidence provided in the dossier from the health technology developer. While the G-BA generally follows IQWiG's recommendations, it has the discretion to overrule them—something that occasionally occurs [18,19].

To promote a more cohesive approach to HTA and ultimately increase healthcare efficiency across the continent, the European Commission, European Union (EU) Member States, and European Economic Area (EEA) countries have supported collaboration across HTA bodies (HTAb) since the 1980s [9,12,20]. Collaborative HTA work in Europe has been conducted principally under the umbrella of the European Network for Health Technology Assessment (EUnetHTA), an initiative (co-)financed by the EC. EUnetHTA was established "to create an effective and sustainable network for HTA across Europe that could develop and implement practical tools to provide reliable, timely, transparent, and transferable information to HTAs in EU Member States and EEA countries" [21].

After almost 20 years of voluntary cooperation, a sustainable framework for European HTA collaboration was created with the adoption in December 2021 of regulation (EU) 2021/2282 on HTA (HTAR) [1]. This regulation, based on the lessons learned during EUnetHTA, entered into force in January 2022 and following a three year preparatory period is applicable as of January 12, 2025 [22,23]. Its field of mandatory application is limited to MP and certain high-risk MD. During the preparatory period, processes created, tested, and revised under EUnetHTA were reviewed and revised where needed by the members of the different subgroups of the Health Technology Assessment Coordination Group (HTACG).

This article aims to describe the objectives and principles of the HTAR and to highlight the structural similarities and differences amongst HTAb in Europe, while emphasizing their collaboration and support of the HTAR.

2. Comparative analysis of European HTA organizations

2.1. Methods

To illustrate the diversity of HTA systems in Europe that ultimately share a common goal, an analysis was performed as a cross-sectional online survey. European HTAb were invited to answer an online questionnaire from July 8 to August 25, 2024, circulated through the Heads of HTA Agencies Group. Created in 2021, the Heads of HTA Agencies Group is an independent group of 32 European healthcare agencies working together to advance strategic collaboration on HTA [24].

The survey was sent by email to 33 HTAb. They had 7 weeks to complete the questionnaire. In absence of a response, two email reminders were sent.

The questionnaire was developed by the authors of this study, in English only using the EU Survey platform. It comprised 11 multiple choice questions yielding categorical variables. The questions were structured to describe the HTAb organization, remit and scope, and follow-up questions were asked based on responses to the primary questions. Optional free text explanations were possible throughout the survey to further detail the national HTAb process.

The data collected from the survey was self-declared by the HTAb themselves and not verified by the authors with the exception of a double submission by one organization and a clarification request to another. Descriptive statistics were used to report and display results.

2.2. Results of the survey

Of the 33 HTAb invited to participate, 27 (82%) representing 16 different EU/EEA countries (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, The Netherlands, Norway, Portugal, Romania, Spain, Sweden) responded to the online questionnaire. The majority of the HTAb (22 of the 27 respondents, 81%) have a national remit, although 5 regional organizations also responded. Older HTA organizations (i.e., those created >10 years ago) represented 24 of the 27 respondents (89%). Two indicated they were created 6–10 years ago and one 1–5 years ago. 67% (18/27) indicated that their organization is independent from the Ministry of Health.

The HTA process at national level follows regulatory approval for MP and CE marking for MD. In both cases, HTA is followed by pricing negotiation. Notably, some HTAb are involved in this entire process with one third (9/27) indicating that they are also regulators and 15% (4/27) responsible for and/or involved in the negotiation of prices.

The results of the questionnaire confirmed the heterogeneity of scope of HTAb in Europe. Despite their diversity, almost half (48%,13/27) assess both MPs (including or not vaccines) and MDs.

Only 8 HTAb (30%) indicated that they assess all categories (MP including vaccines, MD, diagnostic and therapeutic procedures, public health interventions and/or screening programs) (see Fig. 2 for details). The others have a more restricted scope (see table 1 and Fig. 2 for details). Among the HTAb who assess MP only 43% (10/23) indicate that they assess all MP, with the majority (13/23, 57%), evaluating only certain MP. 63% (17/27) of respondents reported assessing MD.

The selection of evaluated products is also variable and may be based on their place of intended use (inpatient vs outpatient), whether the product in question is a new substance or an extension of indication or based on perceived risk or cost of the product. It is more complicated to pinpoint a strong commonality in the criteria for those who assess MD, although several HTAb cited that they conduct their assessment based on a request from an external organization. About half (52%, 14/27) of the responding HTAb assess diagnostic and therapeutic procedures and half of those HTAb (50%, 7/14) assess all diagnostic and therapeutic procedures. All HTAb indicating they assess diagnostic and therapeutic procedures also indicate they assess some MD. Finally, only 44% (12/27) reported conducting public health interventions and/or screening program assessments. The scope of these assessments varies quite greatly, nevertheless 58% (7/12) noted oncological and newborn screening in their comments. Fig. 2. illustrates the variation in the scope of health technologies assessed in European HTAb.

The HTA process is also highly variable, 89% (24/27) of HTAb include at least a clinical assessment and an economic assessment,

Table 1
Summary of main results from the comparison of European HTA bodies' structure.

Organizational characteristics	n (%) *N* = 27
Coverage	
• national	22 (81%)
• regional	5 (19%)
Establishment	
• >10 years ago	24 (89%)
• 6–10 year ago	2 (7%)
• 1–5 years ago	1 (4%)
Remit outside of HTA	
• none	14 (52%)
• regulatory body	8 (30%)
• pricing body	5 (19%)
HTA scope[a]	
• medicinal products	23 (85%)
◦ incl. vaccines	15 (65%)
◦ excl. vaccines	8 (35%)
• medical devices	17 (63%)
• act	14 (52%)
• public health interventions and/or screening program	12 (44%)
HTA domains[a]	
• clinical	27 (100%)
• economic	24 (89%)
• environmental impact	4 (15%)
• organizational impact	13 (48%)
• ethical analysis	11 (41%)
• social analysis	11 (41%)
Starting point of the assessment[a]	
• request from HTD	17 (63%)
• request from Ministry of Health	13 (48%)
• request from other stakeholder(s)	15 (56%)
Data used for HTA[a]	
• submission dossier from HTD	22 (81%)
• data or analysis from literature	21 (78%)
• data or analysis generated by your organization	16 (59%)
• data or analysis generated by another organization	12 (44%)

Totals may not add up to 100% due to rounding.
[a] Multiple choice possible.

while 48% (13/27) include an organizational impact assessment. Only 40% (11/27) of HTAb reported including ethical and social domains in their assessments. Of note, several HTAb commented that they also include a patient perspective (or patient-based evidence) or legal domains in their assessments. Interestingly, one HTAb reported including a section detailing knowledge gaps in their assessment. Several organizations are basing their assessment on extensive domains, e.g., clinical, economic, organizational, ethical, social or legal (see Fig. 3 for details).

Requests for an HTA assessment most often originate from an HTD (63%, 17/27) and/or the ministry of health (48%, 13/27). Many HTAb (56%, 15/27) also indicated that requests could originate from stakeholders including: patients/patient organizations, the general public, other governmental organizations, physicians' associations, insurers, hospital committees and local authorities, national or international research projects.

The core of an HTA assessment is data and, as with other aspects of HTA, the type of data on which these assessments are based varies. 81% (22/27) of HTAb reported using data or analyses from a dossier submitted by the HTD and 78% (21/27) reported using data or analysis from literature. In terms of generating additional data or analyses (e.g. health economics models or contextualizing data) 59% (16/27) can use data or analyses generated by their organization whereas 44% (12/27) can use data or analysis generated by another organization. Interestingly, 7% (2/27) of HTAb indicated they only used the data or analyses contained in the HTD's submission dossier. One HTAb reported that it only uses data or analysis from the published literature, while another indicated that its reports are based on the European Public Assessment Report (EPAR) issued by the European Medicines Agency and on data or analyses generated by another organization. In most cases, however, the HTAb reported that they used a variety of data in their reports.

3. Description of the HTAR

The legislative process of passing the HTAR followed a long pathway. The first proposal for the HTAR was published by the European Commission on January 31, 2018. The European Parliament closed its first reading position in February 2019 while the Council adopted its first reading position in November 2021.

Shortly after the vote of the European Parliament in early second reading in December 2021, the Regulation was adopted in December 2021 [25]. The HTAR entered into force on January 11, 2022 and, following a 3-year implementation period, is applicable as of January 12, 2025. Although HTA can be applied to many areas, the mandatory scope of the HTAR is limited to MP and certain high-risk MD. Like any European regulation, this text applies automatically and uniformly to all EU countries as soon as it enters into force, without needing to be transposed into national law. It is binding in its entirety on all EU countries [26]. The HTAR is also "relevant" to EEA countries meaning that they can choose to participate to the Health Technology Assessment Coordination Group (HTACG, see 3.1 for further details) and HTAR processes, but unlike for member states, the HTAR is not automatically applicable.

While European HTAb have now collaborated on HTA for many years, it was principally on a voluntary basis with partial funding from the European Commission. The HTAR provides a legal and sustainable framework for European HTA. It notably introduces the basis for the production of joint scientific consultations (JSC) and joint clinical assessments (JCA) as well as joint work on methodological guidance and the identification of emerging health technologies.

The regulation calls for the EC to adopt 6 Implementing Acts by January 2025 to further define rules of procedure. Implementing acts "enable the Commission – under the supervision of committees consisting of EU countries' representatives – to set conditions that ensure that EU laws are applied uniformly [26]." The six implementing acts provided for the HTAR will establish rules for JSC for MP and MD, JCA for MP and MD, the exchange of information with the European Medicines Agency (EMA), and finally the management of conflicts of interest.

3.1. Description of the governance

The HTAR called for the creation of a Member State Coordination Group on HTA (i.e., the HTACG) composed of, but not limited to, representatives from HTAb from all member states. It is established with responsibility for overseeing the conduct of JCA and other joint work within the scope of this Regulation [1]. It is assisted by 4 subgroups also detailed in the HTAR to carry out specific activities:

- Joint clinical assessments,
- Joint scientific consultations,
- Emerging health technologies,
- Methods and procedures.

The HTACG and its subgroups operate in two configurations: one for MP and one for MD. The European Commission provides administrative, technical and information technology support through the HTA Secretariat and can also facilitate cooperation with the EMA, expert panels and the MD Coordination Group. Finally, the regulation established a stakeholder network that can also provide input to the work of the HTACG and its subgroups upon request [1,27]. Fig. 1 illustrates the governance of the HTAR.

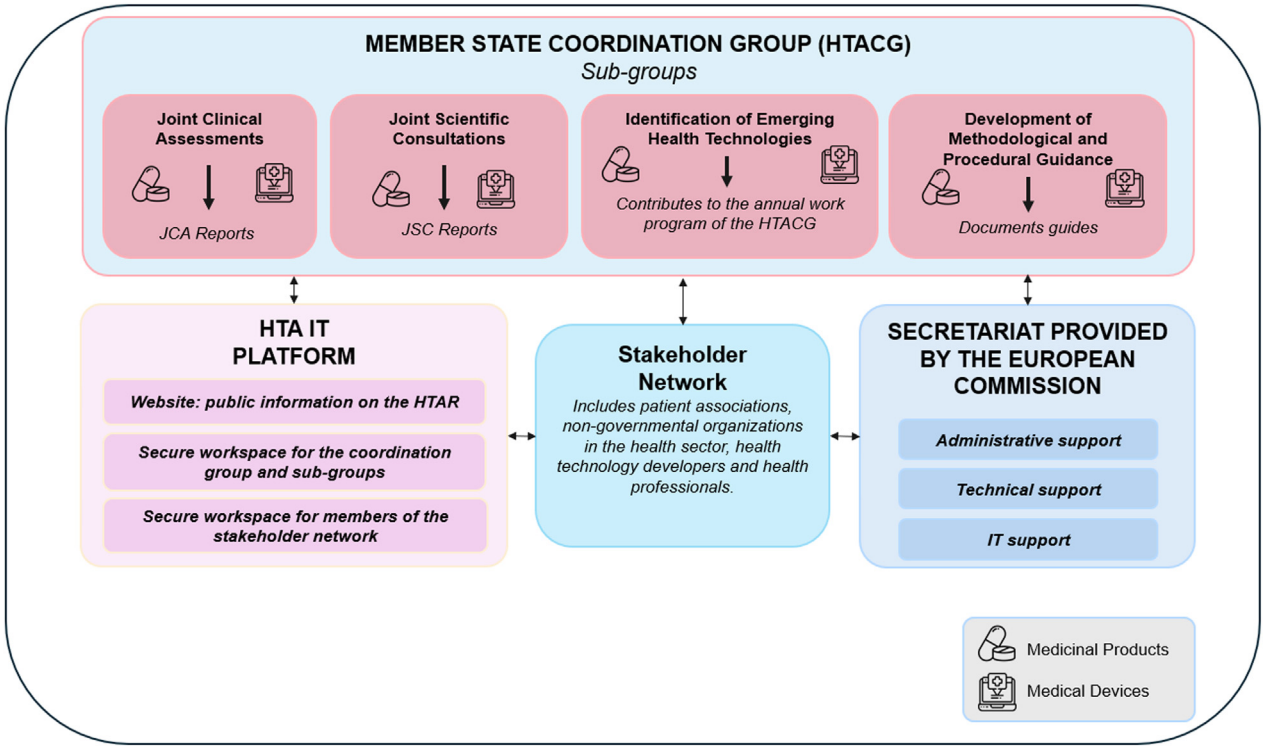

Fig. 1. HTAR governance - adapted from the Factsheet "Implementing the EU Health Technology Assessment Regulation".

3.2. Joint work

Joint work under the HTAR covers only the scientific and clinical aspects that are common to HTA: i.e., identification of a health problem, the examination of the technical characteristics of the health technology under assessment, its relative safety, and its relative clinical effectiveness. Non-clinical domains, such as health economic evaluation, are not included in the mandatory scope of the regulation but could be addressed within the voluntary cooperation also introduced by the HTAR.

The HTAR establishes a common European framework for:

- ***Joint clinical assessments (JCAs)*** are a scientific analysis of the existing relative efficacy and safety data in comparison with existing therapies. The dossier submitted by the HTD and the report endorsed by the coordination group will be based on the assessment scope that defined the relevant Population, Intervention, Comparators and Outcomes (PICOs) for each JCA procedure. They will also include an analysis of the certainty of the results, describing the strength and limitation of the methods used to generate the data. However, JCAs should not contain any value judgement, ranking of health outcomes, conclusions on the overall benefit or clinical added value, or any position in the treatment pathway as these conclusions depend on national healthcare context and situation. Moreover, they should not affect the discretion of member states to draw conclusions on pricing and reimbursement, which may ultimately be based on clinical and non-clinical domains. JCA for MP will be conducted in parallel with the

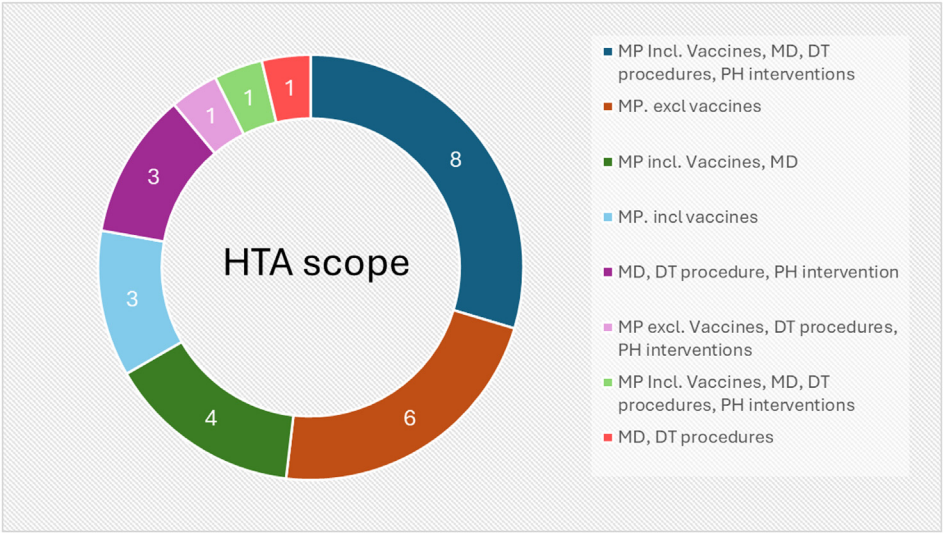

Fig. 2. Details on the scope of the 27 responding HTA bodies. *MP, medicinal product, MD, medical device,* pH, *public health.*

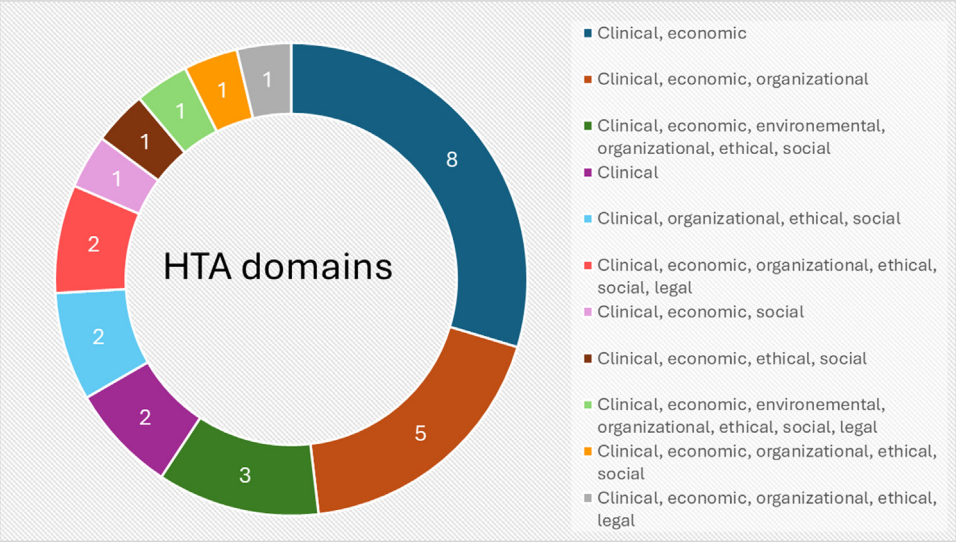

Fig. 3. HTA domains included in national processes of the 27 responding HTA bodies.

marketing authorization procedure. The starting point of JCA for MD will be defined in the relevant implementing act, which was unavailable at the time this article was written;

- ***Joint scientific consultations (JSCs)*** which consist of exchanges with health technology developers (HTD) before the finalization of the clinical development plan for their pivotal trial with the aim of facilitating the generation of comparative evidence expected for relevant HTA and subsequent JCA [1,28];
- ***Procedures and methodological guidance*** for the preparation of JCA reports and JSC outcome documents;
- ***Reports on emerging health technologies*** expected to have a major impact on patients, public health or healthcare systems.

For MP, the regulation is applicable according to a stepwise calendar: 2025 for all new oncology products and advanced therapy medicinal products (ATMP); 2028 orphan MP will be added to the joint work, and by 2030, all products approved through the centralized procedure (i.e. via the EMA) will be subject to a JCA. For MP, the HTAR covers all products that are approved through the centralized procedure whereas the product selection for MD and in-vitro diagnostics will be done via dedicated Implementing Acts at least every two years. Unlike JCA, JSC are not obligatory. They are conducted on request from the HTD. Each request is subject to a published selection criteria and the final report is non-binding.

The HTAR marks the culmination of EUnetHTA and the creation of a sustainable framework. It does this by formalizing and standardizing HTAb collaboration at the European level with five notable changes:

- ***A single submission file***: JCA will be conducted on the basis of a unique submission dossier from the HTD. Data submitted at the European level cannot be re-submitted at the national level. Complementary analyses may, however, be requested;
- ***The PICO framework***: JCA will be based on an assessment scope defined around 4 major concepts: the Population(s), the Intervention(s), the Comparator(s) and the Outcome(s) relevant for the assessment of the health technology. The assessment scope will be consolidated by the JCA subgroup and will be inclusive to reflect the needs of the member states;
- ***The reuse of JCA at the national level*:** member states are required to give due consideration to JCA Reports in their national or regional HTA process;
- ***The JSC selection criteria***: with the establishment of a sustainable framework for JSCs, eligibility and selection criteria were introduced: a) unmet medical needs; b) first in class; c) potential impact on patients, public health or healthcare systems; d) significant cross-border dimension; e) major Union-wide added value; or f) EU clinical research priorities;
- ***The Horizon Scanning* reports** identifying emerging health technologies expected to have a major impact on patients, public health or healthcare systems will be prepared and used to establish the annual work program of the coordination group on HTA.

4. Discussion and conclusions

The comparative analysis of HTA organizations across Europe reveals substantial variations in scope, remit, data used, and domains included in their evaluation. These differences can be attributed to diverse healthcare systems, policy environments, and historical developments in each country. Societal preferences can also influence national process and organization of healthcare.

Our study highlights the heterogeneity of HTA organizations in Europe, particularly in terms of their organizational structures and the scope of technologies assessed. For instance, some countries have HTAb with comprehensive evaluation scopes covering pharmaceuticals, MD, diagnostic and therapeutic procedures, and public health interventions. In contrast, others have a narrower scope, assessing only MD or MP, for example.

This analysis is, however, strongly limited by the number of participants. Most of the respondents (27 HTAb from 16 European countries) were from organizations that have been established for >10 years. They do not necessarily represent countries where the HTA system is not yet established or has a more nascent process. Nevertheless, the many similarities across HTA bodies suggested by the data underlines the need for enhanced collaboration and knowledge sharing among HTAb both to reduce duplication of efforts for national HTA authorities and to ensure the long-term sustainability of EU HTA cooperation.

The implementation of the HTAR aims to address some of these disparities by promoting convergence in HTA methodologies and facilitating JCA. The regulation's emphasis on joint work is expected to reduce duplication of efforts, streamline processes, and improve the overall quality of assessments. Nevertheless, the need for capacity

building among the subgroup representatives should not be underestimated. Ensuring that all member states have the necessary resources and expertise to conduct high-quality assessments and respect their obligation vis-à-vis the HTAR is critical for the successful implementation.

To meet these challenges, several tenders were opened by the European Commission through the EU4Health program. A call for tenders to build capacity and knowledge for the implementation of the EU HTAR was published in March 2024 with the aims to (i) provide training services to ensure EU HTAb consolidate their knowledge and experience on joint HTA work and (ii) establish a competency framework on the technical expertise required for carrying out JCAs and JSCs for both MP and MD. In August 2024, a call for tender was published to establish a framework contract for the funding of JCAs and JSCs as per Article 27 of the HTAR. The latter seeks to support HTAb to prepare for their participation in JCAs and JSCs as assessors or co-assessors. In addition to these tenders, member states will have to support the implementation of the HTAR through their HTAb to ensure its success and to meet the obligations of the HTAR without compromising their national activities.

The governance structure of the HTAR reflects the distribution of responsibilities in healthcare within the European Union. While certain activities, such as the authorisation of health products entering the common market, can be centralised at the EU level, the regulation and funding of healthcare remain the responsibility of individual Member States. They may indeed differ in their approaches to healthcare funding and social insurance, as well as in their policies on coverage, reflecting national and societal preferences.

Under the HTAR, scientific governance and responsibility are entrusted to a group of representatives from EU Member States. This ensures that HTA reports address the diverse needs of all Member States, facilitating their national-level decisions on reimbursement and pricing. While the centralisation of the administrative support hosted by the European Commission and scientific assessment is desired, the creation of a dedicated EU agency that would provide unique conclusions to recommend coverage of new health product for the entire European union would not be in line with the European principles on distribution of competences.

Overall, despite some heterogeneity in HTAb (e.g. HTA scope, domains of included in their assessments, types of data included) at a national level, they all share a common objective in assessing the appropriateness of the coverage of new health products and interventions with regards to their clinical value. HTA system ultimately contribute to efficient use of healthcare resources and improve the quality of care for patients. The HTAR is a great example to illustrate this common objective between HTA bodies. The HTAR offers numerous opportunities for collaboration. Joint assessments will foster a culture of mutual learning, allowing countries to benefit from shared expertise and data while ensuring the rigorous and transparent assessment of new health technologies. Moreover, a more unified approach to HTA could accelerate the adoption of new and effective technologies at the continental level, ultimately improving patient outcomes across Europe. The regulation also encourages greater involvement of stakeholders and experts, including patients and healthcare providers, in the HTA process. By incorporating diverse perspectives, HTA organizations can enhance the relevance and impact of their assessments. Nevertheless, while mutual understanding was gained during the previous voluntary cooperation in Europe on HTA and despite intensive preparatory work undertaken by the HTACG and the European Commission, there remains a significant distance to cover before the full establishment of an efficient, relevant, and useful system for all stakeholders. January 2025, marking the beginning of joint productions, will be the first step in implementing a system that will necessarily evolve based on the experience gained.

Declaration of competing interest

The authors have no competing interests relevant to this paper to disclose.

CRediT authorship contribution statement

Judith Fernandez: Writing – review & editing, Writing – original draft, Supervision, Data curation, Conceptualization. **Paul de Boissieu:** Writing – original draft, Conceptualization. **Margaret Galbraith:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization.

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References

[1] 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). Offic J Eur Union 2021;22 L 458/1-32. http://data.europa.eu/eli/reg/2021/2282/oj.

[2] O'Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: a milestone in international collaboration. Int J Technol Assess Health Care 2020;36(3):187–90. doi: 10.1017/s0266462320000215.

[3] Direction de la recherche, des études, de l'évaluation et des statistiques. les dépenses de santé en 2022. résultats des comptes de la santé. Edition Disponible; 2023. [En ligne] 2023. https://drees.solidarites-sante.gouv.fr/sites/default/files/2024-02/CNS2023MAJ280224.pdf [cité le 5 nov 2024].

[4] Vincent Rajkumar S. The high cost of prescription drugs: causes and solutions. Blood Cancer J 2020;10(6):71. doi: 10.1038/s41408-020-0338-x.

[5] Rome BN, Egilman AC, Kesselheim AS. Trends in prescription drug launch prices, 2008-2021. JAMA 2022;327(21):2145–7. doi: 10.1001/jama.2022.5542.

[6] Cristea M, Noja GG, Stefea P, Sala AL. The impact of population aging and public health support on EU labor markets. Int J Environ Res Public Health 2020;17(4):1439. doi: 10.3390/ijerph17041439.

[7] Décret n°67-441 du 5 juin. Relatif aux conditions de remboursement des médicaments aux assurés sociaux. 1967. https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000870187.

[8] Loi n° 2004-810 du 13 août. relative à l'assurance maladie. 2004. https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000625158.

[9] Banta D, Jonsson E. History of HTA: introduction. Int J Technol Assess Health Care 2009;25(Suppl 1):1–6. doi: 10.1017/s0266462309090321.

[10] Banta D, Kristensen FB, Jonsson E. A history of health technology assessment at the European level. Int J Technol Assess Health Care 2009;25(Suppl 1):68–73. doi: 10.1017/s0266462309090448.

[11] European Commission. Directorate-General for Health and Food Safety. Mapping of HTA methodologies in EU and Norway. 2017. https://health.ec.europa.eu/system/files/2018-01/2018_mapping_methodologies_en_0.pdf [cité le 12 sept 2024].

[12] European Parliament. Strengthening of the EU cooperation on health technology assessment (HTA). 2018. https://www.europarl.europa.eu/RegData/etudes/BRIE/2018/621813/EPRS_BRI(2018)621813_EN.pdf.

[13] Fontrier AM, Visintin E, Kanavos P. Similarities and differences in health technology assessment systems and implications for coverage decisions: evidence from 32 countries. Pharmacoecon Open 2022;6(3):315–28. doi: 10.1007/s41669-021-00311-5.

[14] NICE. Technology appraisal guidance. 2025. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance.

[15] Epstein D, Espín J. Evaluation of new medicines in Spain and comparison with other European countries. Gac Sanit 2020;34(2):133–40. doi: 10.1016/j.gaceta.2019.02.009.

[16] Serrano-Aguilar P, Asua-Batarrita J, Molina-López MT, Espallargues M, Pons-Rafols J, García-Armesto S, et al. The Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System (RedETS). Int J Technol Assess Health Care 2019;35(3):176–80. doi: 10.1017/s0266462319000205.

[17] Jommi C, Garau M. Around the world in HTAs: italy – what's next? 2023. https://www.ohe.org/insight/around-the-world-in-htas-italy.

[18] Gemeinsamer Bundesausschuss. The benefit assessment of medicinal products in accordance with the German Social Code, book five (SGB V), section 35a. 2024. https://www.g-ba.de/english/benefitassessment.

[19] Pownell A. Your guide to the German HTA system. Answers to the 10 most commonly asked questions. Version 5.0. 2024. https://germanmarketaccesssimplified.com/wp-content/uploads/2024/07/Introduction-to-the-German-HTA-system-v5.0-1.pdf.

[20] Urbina I, Adams R, Fernandez J, Willemsen A, Hedberg N, Rüther A. Advancing cooperation in Health Technology Assessment in Europe: insights from the EUnetHTA 21 project amidst the evolving legal landscape of European HTA. Int J Technol Assess Health Care 2024;40(1):e75. doi: 10.1017/S0266462324004689.

[21] Kristensen F. Development of European HTA: from vision to EUnetHTA. Michael 2012;9:147–56. https://www.michaeljournal.no/article/2012/03/Development-of-European-HTA-from-Vision-to-EUnetHTA [cité le 12 sept 2024].

[22] Imaz-Iglesia I, Wild C. EUnetHTA's contribution to the new legal framework for health technology assessment cooperation in Europe. Int J Technol Assess Health Care 2022;38(1):e50. doi: 10.1017/s026646232200037x.

[23] Brinkhuis F, Julian E, van den Ham H, Gianfrate F, Strammiello V, Berntgen M, et al. Navigating the path towards successful implementation of the EU HTA Regulation: key takeaways from the 2023 Spring Convention of the European Access Academy. Health Res Policy Syst 2024;22(1):74. doi: 10.1186/s12961-024-01154-2.

[24] The Heads of HTA agencies (HAG) 2022. https://htahag.eu/ [cité le 12 sept 2024].

[25] European Commission. Health Technology Assessment Regulation. 2021. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6771 [cité le 12 sept 2024].

[26] Consolidated version of the treaty on the functioning of the European Union. Offic J Eur Union 2012 C 326/49-90. http://data.europa.eu/eli/treaty/tfeu_2012/oj/eng.

[27] European Commission. Directorate-General for Health and Food Safety. Factsheet - implementing the EU Health Technology Assessment Regulation. 2023. https://health.ec.europa.eu/publications/factsheet-implementing-eu-health-technology-assessment-regulation_en [cité le 12 sept 2024].

[28] Galbraith M, Guilhaume C, Bélorgey C. Early dialogues for pharmaceutical products in European Network for Health Technology Assessment Joint Action 3: what was done and where to go in the future. Int J Technol Assess Health Care 2022;38(1):e30. doi: 10.1017/s0266462322000083.