



HAG Strategic Plan 2025-2028

HAG
HEADS OF HTA
AGENCIES GROUP

HAG Strategic Plan 2025-2028

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Message from the Chairs

We are pleased to present the Strategic Plan 2025–2028 of the Heads of HTA Agencies Group (HAG), which outlines our shared vision and priorities for the years ahead. This document reflects the strong commitment of HTA bodies across Europe to work together in shaping an efficient, responsive, and sustainable health technology assessment (HTA) ecosystem.

The evolving landscape of healthcare, marked by scientific innovation, demographic shifts, emerging health threats, and increasing societal expectations, compels us to act with foresight and unity. Our strategy sets a common direction to address these challenges and to seize opportunities for greater collaboration and impact, particularly in this period of the gradual application of the EU HTA Regulation.

A key feature of this strategic plan is the definition of the Group's mission, vision and values, which will serve as the foundation for our collective actions. These guiding principles define who we are as a network, what we aim to achieve, and the standards by which we hold ourselves accountable. They are the essential pillars in the pursuit of our common goals.

In close coordination with the European Commission and the HTA CG, we reaffirm the need for robust and transparent decision-making, the integration of real-world evidence and digital tools, to support national and European processes under the new EU HTA Regulation. At the heart of this strategy lies a commitment to promote the value of HTA in European healthcare systems while strengthening capacity, collaboration, communication and ensuring the sustainability of the collaboration. These aspects will be key to enable timely, fair and sustainable access to health technologies with added benefit to patients.

This strategy is the result of broad consultation and collective reflection. Its success will depend on the continued engagement of all HAG members and close cooperation with our partners — patients, healthcare professionals, regulatory bodies, policymakers, general public and other relevant stakeholders.

We look forward to working together to implement these strategic objectives to fulfil our collective vision and advance the role of EU/EEA HTA as an enabler of timely, fair and sustainable access to health technologies with added benefit.



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Chair of the HAG
INFARMED, Portugal



Agneta Karlsson

Vice-Chair of the HAG
TLV, Sweden



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Vice-Chair of the HAG
HAS, France

Executive Summary

Health technology assessment (HTA) is a scientific evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing health technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.¹

With the entry into application of the Health Technology Assessment Regulation on 12 January 2025, a new EU framework has been established to evaluate health technologies by fostering enhanced cooperation and coordination among EU Member States. This marks a major milestone of the utmost importance for public health and for European HTA Collaboration.

The Heads of HTA Agencies Group (HAG) is an independent group of European HTA bodies working together to advance strategic collaboration on HTA. The HAG plays an important role on supporting strong strategic partnerships and to promote effective and efficient solutions for a European HTA collaboration and to enhance the impact of HTA in decision-making and on European healthcare systems. By facilitating the information and experience sharing between organizations. Supporting cooperation and address key strategic issues for the European HTA network, such as capacity building, work-sharing and exchange of best practices. And by advising policy makers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA.

Since its foundation the HAG has taken important steps to support the EU HTAR implementation, including the preparation of national systems and capacities and raising awareness among different stakeholders of the importance of HTA in Europe.

The HAG Strategic Plan (SP) outlines the mission, collective vision, priorities, and key actions that will steer the Heads of HTA Agencies Group and the broader EU Health Technology Assessment collaboration until 2028.

¹ As defined by the Regulation (EU) 2021/2282 on health technology assessment.

The Strategic Plan serves as a roadmap for joint efforts within the European HTA collaboration. The Strategic Plan is structured around six strategic focus areas:

1. Enhance HTA capability, capacity and knowledge across the EU/EEA HTA bodies
2. Create strategic alliances with relevant stakeholders
3. Strengthen voluntary and strategic cooperation
4. Promote the value of HTA in European healthcare systems
5. Strengthen HAG communication
6. Ensure sustainability of the collaboration

The HAG Strategic Plan also reaffirms the commitment of the HAG and of European HTA bodies to scientific excellence and operational efficiency and to contribute to the successful and effective implementation of the EU HTA Regulation. It pursues a collective vision in which HTA contributes to timely, fair and sustainable patient access to health technologies with added benefit.

The Plan considers as essential governing features the close collaboration between the European Commission, the HTA Member States Coordination Group, the national HTA bodies, the European Medicines Agency and national competent authorities and other relevant stakeholders.

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List of abbreviations

AI	Artificial Intelligence
EEA	European Economic Area
EMA	European Medicines Agency
EMANS	European medicines agencies network strategy
EU	European Union
HAG-INSIGHT	Head of Agencies Group Initiative for Knowledge and Skill Enhancement in Health Technology Assessment Regulation
HAG	Heads of HTA Agencies Group
HAG COM WG	HAG Communication Working Group
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
HTACG	Member State Coordination Group on HTA
HTAR	Health Technology Assessment Regulation
IHSI	International Horizon Scanning Initiative
IVDR	In Vitro Diagnostic Medical Devices Regulation
MDR	Medical Device Regulation
MEDEV	Medicine Evaluation Committee
NCAPR	National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers
NEED	Needs Examination, Evaluation and Dissemination project
SUSTAIN-HTA	Support Utilisation of Sustainable and Tailored INnovative methods for HTA Initiative
TSI	Technical Support Instrument

Vision, Mission and Values



Vision

A Europe in which HTA contributes to timely, fair and sustainable patient access to health technologies with added benefit



Mission

To support strong strategic partnerships and to promote effective and efficient solutions for a European HTA collaboration

To fulfil its mission, the HAG will:

Facilitate dialogue and an open exchange of information between EU/EEA HTA bodies

Support the cooperation and address key strategic issues for the network, such as capacity building, work-sharing and exchange of best practices

Advise policy makers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA

Support the joint work under the Regulation (EU) 2021/2282 on health technology assessment (HTAR)

Values

The HAG represents a strong and united voice in favour of European HTA cooperation. In line with the objective of the **General principles of good cooperation in the field of health technology assessment** (available [here](#)), the members of the HAG adopted three core values which will guide the collective strategy and action of HTA bodies at European level.

Trust

between European HTA bodies based on good faith, fairness and respect for all stakeholders and on common frameworks to ensure the success of HTA activities and the achievement of shared goals.

Collaboration

is the most fundamental value of European HTA cooperation. HTA bodies and stakeholders benefit from an engaging and participatory collaboration, based on open and transparent dialogue and mutual respect.

Transparency

in the relationship between all HTA bodies and stakeholders to promote trust, credibility and the value of HTA amongst all parties involved, including European citizens, while also supporting transparency of the evidence underlying decision making.

Strategic areas for 2025-2028

The **HAG Strategic Plan outlines the HAG's collective vision, mission, priorities and key actions for 2025-2028**, reinforcing our commitment to strengthening scientific excellence, operational efficiency and stakeholder engagement.

By aligning with the evolving regulatory and policy landscape, including the implementation of the HTAR, this strategy aims to enhance the impact of HTA on European healthcare systems and builds on **six strategic areas**:

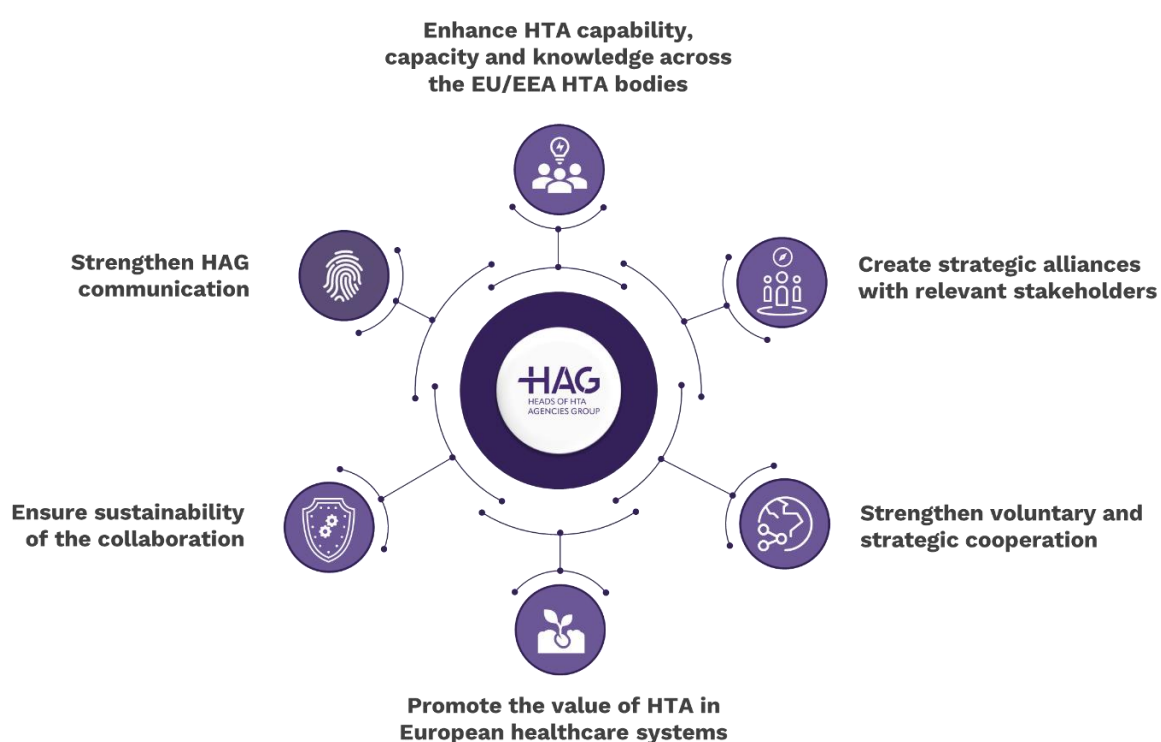


Figure 1. The six strategic areas in the Heads of HTA Agencies Group (HAG) Strategic Plan 2025-2028

This document serves as a roadmap for our joint efforts, guiding the network towards a future where evidence-driven assessments contribute to better health policies and improved patient care.

Enhance HTA capability, capacity and knowledge across the EU/EEA

The development of HTA related activities requires specialised knowledge and skills, grounded in the principles of evidence-based medicine, state-of-the-art methods, and fit-for-purpose scientific and clinical evidence.

Similarly, the implementation of the HTAR entail close and intensive collaboration at the European level to conduct joint work in a timely manner, striving for the highest level of expertise.

Therefore, it is important to enhance the capabilities and capacity of HTA bodies across Europe and provide training to their professionals. Continuous training ensures that professionals are well-informed and capable of performing joint work using the methodologies, practices, and procedures adopted by the Member State Coordination Group on HTA (HTACG). By fostering a culture of learning and professional development, this will strengthen the ability of HTA bodies to conduct high-quality assessments, make informed decisions, and adapt to the evolving healthcare landscape.

Moreover, it is recognised that there are EU/EEA Member States where HTA frameworks, methodologies, and activities are still nascent. In this context, national capacity-building developments gain special relevance.

Investing in capacity-building and training activities not only enhances individual knowledge and competencies but also reinforces the overall effectiveness and sustainability of the EU/EEA HTA collaboration, contributing to the success of the HTAR. The sustainable application of HTA under the HTAR can ultimately help to improved health outcomes for patients in Europe.

Goals and actions to implement to enhance HTA capability, capacity and knowledge across the EU/EEA

GOALS	ACTIONS TO IMPLEMENT
[1] Reinforce the scientific and technical capabilities of HTA bodies across EU/EEA	<ul style="list-style-type: none">– Support the implementation of the Head of Agencies Group Initiative for Knowledge and Skill Enhancement in Health Technology Assessment Regulation (HAG-INSIGHT) initiative to strengthen the long-term capacity and expertise of EU HTA bodies in executing the HTAR effectively and sustainably.– Monitor and engage with other EU capacity-building initiatives and projects (e.g. Support Utilisation of

Sustainable and Tailored INnovative methods for HTA Initiative [SUSTAIN-HTA] and TSI initiatives).

[2] Maintain a standing platform for sharing any relevant information and best practices

- Promote frequent internal discussions around practices, developments and outstanding issues about HTA collaboration in Europe.
 - Support the HTACG in strategic discussions, high-level forums and events dedicated to methodologies and emerging areas of HTA.
 - Maintain and support the activity of the HAG Digital Medical Devices Working Group.
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Create strategic alliances with relevant stakeholders

Past global health challenges have highlighted the importance of cross-border cooperation and collaboration between different decision-makers (e.g. regulatory authorities, HTA bodies and payers) and stakeholders (e.g. healthcare professionals, patient representatives and industry). The HAG sees the need for a value chain of evidence that starts at horizon scanning and is reinforced by the work on joint scientific consultations for the benefit of all decision-makers in the processes downstream.

Engaging with other authorities or bodies competent in healthcare is particularly important in the context of the ongoing discussions on the Pharmaceutical Legislation Reform, the Medical Device Regulation and the *In Vitro* Diagnostic Regulation, the European Health Data Space Regulation (EHDS), the Artificial Intelligence Regulation, the Critical Medicines Act and other relevant legislative European initiatives that intersect and influence HTA activities.

In order to pursue the goal of promoting the value of health technology assessment in European health systems, it is also important to work continuously with different stakeholders, including policy-makers, mainly at European level. The HAG provides a relevant platform for advising policy makers and relevant EU and national institutions on matters regarding HTA and other developments that intersect and influence HTA activities.

Additionally, whilst respecting the different remits and mandates, cooperation between the regulatory assessments performed by regulatory authorities, and the clinical assessments by HTA bodies is essential to optimise the path to accessibility for health technologies. Evidence generation, optimising data collection, taking advantage of the digital transformation and artificial intelligence technologies, and cooperating to achieve appropriate and transparent presentation of evidence, are topics which could be considered

and discussed in order to improve mutual understanding of efficiency and health outcomes. In this context, it is important to join efforts with the European Commission, the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) and other relevant stakeholders.

Goals and actions to implement to create strategic alliances with relevant stakeholders

GOALS	ACTIONS TO IMPLEMENT
[3] Build synergies and work with key EU bodies, health organisations and global HTA networks	<ul style="list-style-type: none"> – Contribute to initiatives exploring the perspective of different stakeholders on key strategic issues for the European HTA collaboration. – Maintain communication and close collaboration with the European Commission and the HTACG. – Engagement in collaboration platforms between regulatory authorities, HTA organisations, NCAPR and other payer organisations, academia and developers on evidence generation. – Establish communications and joint-activities with the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) and other relevant stakeholders, acknowledging the European Medicines Agencies Network Strategy 2028 (EMANS).
[4] Accompany and engage in the discussion on EU reforms that intersect and influence HTA activities	<ul style="list-style-type: none"> – Maintain and support the activity of the HAG Pharma Legislation Working Group. – Accompany and engage in the discussions on MDR and IVDR, artificial intelligence regulation, EHDS and Critical Medicines Act in areas where they intersect with HTA.

Strengthen voluntary and strategic cooperation

Achieving a European HTA system that respects the needs of its members requires active participation from all EU/EEA Member States. Their engagement brings to the table diversity of perspectives, ensures equitable representation in decision-making and strengthens the

overall credibility of the network. Comprehensive involvement also supports capacity-building among Member States with varying levels of HTA maturity, enabling them to contribute meaningfully to the network. By promoting collaboration and shared ownership of objectives, HAG can build trust, promote mutual understanding, and ensure the long-term success of the European HTA collaboration.

The Joint Nordic HTA Bodies (JNHB) and BeNeLuxA along with any other existing and emerging regional and local initiatives are examples of key international actions. Other cross border collaborations of note that are contributing to a more cohesive Europe and to a greater cooperation among stakeholders like the International Horizon Scanning Initiative (IHSI) the National Competent Authorities on Pricing and Reimbursement (NCAPR), and the Medicine Evaluation Committee (MEDEV) and the Needs Examination, Evaluation and Dissemination (NEED) project.

It's also worth noting that the HTAR outlines the potential for voluntary cooperation in other areas of HTA that can contribute to knowledge-sharing and joint-work regarding HTA. The HAG can act as a common platform for strategic discussion and sharing of practices and experiences in this area.

Goals and actions to strengthen voluntary and strategic cooperation

GOALS	ACTIONS TO IMPLEMENT
[5] Continued collaboration and knowledge-sharing and research beyond the implementation of the HTAR	<ul style="list-style-type: none"> – Act as a platform for the HAG members to discuss the future organisation of the European HTA collaboration. – Support and promote collaborative research aligned with the HAG mission and vision
[6] Convergence of European HTA systems, supporting implementation of joint production and facilitating dialogue and an open exchange of information between EU/EEA Member States.	<ul style="list-style-type: none"> – Map and support the existing cooperation's between HTA bodies across Europe to streamline assessments and decision-making processes (e.g. IHSI, NCAPR, MEDEV and the NEED). – Promote the sharing of relevant work emerging from regional and local cooperation initiatives (e.g. JNHB, BeNeLuxA and others).

[7] Involvement and participation of all EU/EEA Member States in the HAG and in the activities of the European HTA system.	<ul style="list-style-type: none"> – Promote internal collaborative work particularly through working groups and frequent consultation of HAG Members. – Foster the onboarding of new HTA bodies on the HAG.
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Promote the value of HTA in European healthcare systems

The adoption of the HTAR is a major milestone. By addressing strategic issues relevant to HTA bodies and promoting the value of HTA, the HAG can encourage the integration of HTA into healthcare decision-making processes. As the cost of healthcare and health products continue to rise across Europe, the importance of robust HTA processes cannot be overstated as it is a major tool for ensuring the sustainability of European healthcare systems. The HAG members are committed to promoting the value of HTA at national and European level, through the HTAR, to inform decision-making and support an equitable, efficient, and high-quality health system ultimately benefiting citizen and patients with added benefit health technologies. This calls for an awareness among relevant stakeholders - decision-makers, payers, patients, healthcare professionals and institutions - on the importance of HTA and the use of HTA-outcomes in informed decisions.

Goals and actions to promote the value of HTA in European healthcare systems

GOALS	ACTIONS TO IMPLEMENT
[8] Contribute to raising awareness among the different stakeholders of the importance of health technology assessment	<ul style="list-style-type: none"> – Maintain collaboration with the European Commission and other relevant organisations. – Ensure HAG representation and participation in national and regional initiatives and events to promote the HTA value among relevant stakeholders (policy and decision-makers, regulatory authorities, payers, patients, healthcare professionals and institutions). – Continuously advocate for the value of HTA among the public and relevant stakeholders.

Strengthen HAG communication

Effective communication is essential for the HAG to ensure alignment, transparency, and engagement both within the HAG and also with external stakeholders. To achieve our strategic goals, it is crucial to establish clear and structured communication channels that support informed decision-making, promote collaboration, and enhance the visibility of HTA and HTA efforts at the European level.

Targeted actions will need to be implemented to reinforce internal and external communication. This includes the continuous development of the HAG's communication framework including the communication plan by the HAG Communication Working Group (HAG COM WG) and the development and maintenance of secure IT systems, such as the HAG website and suitable platforms for information exchange within the different working groups and the HAG secretariat. The use of the HAG's communication tools, including its website and LinkedIn page, will ensure the dissemination of relevant information about the HAG's activities and the European HTA collaboration to external stakeholders.

These actions are fundamental to facilitate knowledge exchange and information dissemination in general, especially to ensure the successful implementation of the HTAR while promoting a consistent information flow and joint communication from the European level to member states, to complement the information generated at the national level. Any communication activities of the HAG related to the HTAR will be coordinated with the EU Commission and their communication efforts.

Goals and actions to strengthen HAG communication

GOALS	ACTIONS TO IMPLEMENT
[9] Ensuring robust internal capacity	<ul style="list-style-type: none">– Continue to support the activities of the HAG COM WG ensuring the continuous development of the HAG's framework for internal and external communication and engagement.– Maintain internal IT systems and infrastructures (e.g. website, E-mail services and others) that guarantee secure and effective means of communication.
[10] Strengthen public and stakeholder engagement	<ul style="list-style-type: none">– Develop Communication Plans that define strategic orientations, themes and activities.– Use the HAG's communication tools (e.g. website and LinkedIn Page) to promote its activity and the

developments of the European HTA Collaboration in a timely manner.

- Promote and support communication and information actions and initiatives on HTA (e.g. Info Days, HTA Conference) with the relevant stakeholders.
 - Create and/or disseminate information material about the European HTA collaboration.
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Ensure sustainability of the collaboration

Ensuring the sustainability of the European HTA collaboration and the HAG is essential in the pursuit of a Europe in which HTA contributes to timely, fair and sustainable patient access to health technologies with added benefit. In this view, it is essential to ensure that at the national level, HTA bodies have operational and resource capacity to deliver the expected and planned joint work for the upcoming months. In the same way, it is essential to guarantee stable financial resources for the joint work developed under the HTAR. The HAG has an important role advocating for these conditions.

While the HAG already includes 35 members from 25 EU/EEA Member States, it remains a new network created in parallel to the recent implementation of the HTAR that needs to be consolidated in the future. It is therefore a strategic initiative to increase the HAG network and involve more European HTA bodies. With this envisioned growth, it is also important to ensure that the HAG itself has adequate instruments and resources to fulfil its mission and goals.

Goals and actions to ensure sustainability of the collaboration

GOALS	ACTIONS TO IMPLEMENT
[11] Supporting the implementation phase of the HTAR	<ul style="list-style-type: none">– Advocate for the reinforcement of HTA bodies' operational and resource capacity at national level and the continuity of adequate financial resources for the joint work performed under HTAR– Advocate for an efficient use of available resources at European level.
[12] Support the process of evaluating and reporting on the implementation of the	<ul style="list-style-type: none">– Cooperate on the evaluation and reporting on the implementation of the European HTA Regulation.– Promote coordination between HTA bodies to obtain the information needed for the evaluation

**European HTA
Regulation**

[13] Ensuring the long-term continuity and growth of HAG and of the European HTA collaboration

- Promote efficient and effective work-sharing between HTA bodies.
 - Maintain an updated Memorandum of Understanding for the HAG.
 - Guarantee the allocation of the necessary resources for the operation of the HAG while assuring continuity and involvement of all members, including the function of the Secretariat.
 - Ensure that adequate infrastructures and platforms are in place to enable the HAG to carry out its activities.
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Appendix: Background on the Heads of HTA Agencies Group

The EUnetHTA Joint Action 3-specific Heads of Agencies Group was a collaborative initiative designed to enhance European HTA Cooperation on health technology assessment (HTA), supporting implementation of joint work and facilitating dialogue and an open exchange of information between EU/EEA Member States.

Established in 2021, the Heads of HTA Agencies Group (HAG) is its successor and seeks to build on this work and to sustainably establish a network of heads of EU/EEA HTA bodies and provide a high-level forum to raise and discuss strategic matters of relevance for HTA bodies across Europe, especially within the context of the HTA regulation (HTAR), a major milestone for European cooperation on health that entered into force in January 2022 and applies from January 2025.

The HAG is an important bridge to support HTA as a main tool to promote evidence-based decision-making across European healthcare systems. By facilitating the information and experience sharing between organizations' the network can contribute to different areas of HTA. Since its foundation the HAG has taken important steps to support the HTAR's implementation, including the preparation of national systems and capacities and raising awareness among different stakeholders of the importance of HTA in Europe.

Whilst respecting the different remits and mandates, the HAG works closely with the European Commission and the HTACG and supports strategic discussions and high-level forums to ensure the application of the HTAR, the development of the EU HTA collaboration and a coordinated approach to ensure optimal use of available resources.

As of May 2025, the HAG has more than thirty members agencies and bodies representing governmental, public or standalone independent organisations working in healthcare and with HTA missions from EU/EEA Member States.

Following on from the work carried out since its creation, the HAG is now adopting a strategic plan designed to guarantee the network's commitment to the European HTA and healthcare systems, and further creating condition for the HAG to act as a common collective platform of EU/EEA Member States HTA agencies.