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POINT OF VIEW

Use of artificial intelligence to draft a mini-HTA report on a new medical device belonging to class IIb–III

Andrea Messori[1], Sabrina Beltramini[2], Paola Crosasso[3], Claudia Fruttero[4], Melania Rivano[5], Marco Chiumente[1], Maria C Silvani[6]

[1]Scientific Committee of the National Congress, Italian Society of Clinical Pharmacy and Therapeutics (Sifact), 11 October 2025 - Turin
[2]Pharmacy Unit, IRCCS Ospedale Policlinico San Martino, Genova - Italy
[3]Pharmacy Department, S. Giovanni Bosco Hospital, Turin - Italy
[4]SC Farmacia Ospedaliera AO S. Croce e Carle, Cuneo - Italy
[5]Hospital Pharmacy Department, Azienda Ospedaliero Universitaria, Cagliari - Italy
[6]Hospital Pharmacy Unit, Azienda USL Romagna, Ravenna, Italy and President of Sifact

ABSTRACT

The rapid evolution of artificial intelligence (AI) in the pharmaceutical and medical device (MD) sectors has prompted interest in its potential role in supporting health technology assessment (HTA). This editorial presents an innovative project aimed at facilitating and expanding HTA activities for high-risk MDs (Class IIb–III) in Italy, where structured HTA processes for MDs are inconsistently implemented. The project centers on a freely accessible AI-based web tool designed to generate preliminary mini-HTA reports. The tool operates through two steps: users provide essential device information via an online form, and ChatGPT produces a structured draft report, including PICO statements, coverage of the nine EUnetHTA domains, and a preliminary summary of relevant PubMed evidence. Although these AI-generated reports are imperfect and require expert verification and refinement, they offer substantial practical advantages by reducing the initial workload and enabling rapid production of a first draft—within minutes rather than hours. The project includes detailed operational instructions and real application examples, such as an artificial iris device, presented in supplementary appendices. Future developments include the release of an English-language version to support broader international use. While AI cannot replace expert judgment, the editorial highlights its value as an accelerative tool that can streamline early HTA steps and promote more systematic evaluation of MDs across Italian regions. Continued iterative use is expected to improve system performance and enhance integration into HTA workflows.

Keywords: Artificial intelligence, ChatGPT, Medical devices, Rapid mini-HTA report

In light of artificial intelligence's (AI) growing performance in the pharmaceutical field, in terms of both drugs and high-tech medical devices (MDs), the idea for this project was conceived a few months ago. It aims to promote the use of AI in health technology assessment (HTA) and address the need for practical solutions in this area. As the HTA sector for drugs is firmly controlled by the European Medicines Agency (EMA) at the European level and the Italian Medicines Agency (AIFA) at the national level, the project focuses exclusively on MDs.

There are important peculiarities in the Italian context in which this project began, such as the aforementioned absence of a national agency devoted to MDs. The absence of a national regulatory agency has many significant consequences, greatly increasing the heterogeneity of how MDs are managed locally. For example, purchasing decisions can be made at various levels, including regions, local health units, and centralized purchasing offices with procurement jurisdiction over a few provinces. Furthermore, the acquisition process often differs significantly between high- and low-technology devices. Lastly, the extent to which local clinicians are involved in these decisions varies significantly between regions and hospitals.

On the other hand, the main factors that led to the project's development include Italian healthcare professionals' familiarity with ChatGPT and their awareness of the limitations of the proposed procedure (e.g., ChatGPT's variable performance in identifying relevant clinical studies on PubMed).

In Italy, there is a broad consensus on the objective of enhancing the performance of regional centres that produce few, if any, HTA reports annually. A key advantage of our proposed method is that it enables a preliminary version of the HTA mini-report to be generated with minimal effort.

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Corresponding author:
Andrea Messori
email: messori@estar.toscana.it

While these automated HTA reports do need to be carefully verified and often corrected in various sections, we believe that overcoming the hurdle of generating the initial report is an important pragmatic step. All in all, our main objective was to convert regional HTA centres from their current limited production of reports into centres oriented towards the systematic production of HTA reports, at least with regard to Class IIb/III devices. In this regard, we took into account the above-mentioned familiarity of healthcare professionals with ChatGPT, but not with other Large Language Models (LLMs). Furthermore, a key advantage of our ChatGPT-based procedure is its remarkable ease of use.

As previously pointed out, the HTA governance for MDs in Italy reflects the strong regionalization of the entire national health service. Each region is responsible for its healthcare expenditure (including MDs), meaning that the approval and purchase of MDs depend directly on individual regions. This generates inhomogeneity in the availability of MDs across different regions. Attempts to uniform the HTA process across regions are ongoing, particularly thanks to the efforts of AGENAS, a national agency of the Ministry of Health. However, in the case of medicines, it is well-known that the process of developing HTA evaluations took many years. In our view, the main obstacles to homogeneous management of MDs at a national level are the lack of a national agency devoted specifically to MDs and, more importantly, the well-established regionalization of healthcare budgets that affects access to innovative MDs. The lack of structured national platforms and published HTA reports further exacerbates fragmentation.

As a matter of fact, little HTA is carried out in Italy on MDs, and there are numerous well-known situations in which HTA of MDs is absent. Although local resolutions may require HTA to be applied to MDs, and these local processes are endorsed by national legislation, these regulatory norms often do not translate into practice, or only do so to a limited extent. This results in the drafting of just two or three HTA reports per year. This application of HTA in the field of MDs is far from the systematic evaluation that characterizes the EMA and AIFA in the field of medicines.

This article describes, examines and discusses an original project that aims to promote the wider application of HTA for MDs by creating an easy-to-use, freely accessible AI-based web tool.

The tool is outlined below in simple terms, setting out the two steps through which it operates. These steps are as follows:

1. The user fills in an online form containing basic information about the MD (name, company, CND, RDM and technical data sheet information).
2. ChatGPT, currently the most widely used AI tool, analyses the material and produces a well-laid-out draft HTA report containing the following information on the MD in question:
   a) the PICO;
   b) the nine EunetHTA domains;
   c) a summary of the main PubMed studies.

This will obviously be an imperfect report that can be improved, particularly with regard to identifying studies extracted from PubMed. However, professionals working in HTA for MDs will have a practical, fast tool that enables them to start working on something concrete immediately. This means they will be able to generate a preliminary mini-HTA report specific to the MD in question in a very short time (about five minutes). It should be noted that the mini-report produced through AI automation should initially be treated with caution and will certainly require verification, integration and improvement, which the professionals will inevitably have to commit adequate time to.

Hopefully, making these AI-guided mini HTA reports available to a variety of stakeholders and institutions will enhance the application of HTA for MDs. One hypothesis for the development of this project is to make these reports available online to everyone, regardless of the initial proponent (e.g., a pharmacy, an HTA group, a local health authority, a university hospital or a region).

As expected, our assessment of the first operational prototype indicates that the regulatory aspect does not pose any particular problems. However, the articles extracted from PubMed for the MD in question generally require in-depth verification by a professional or local HTA working group.

While it is undeniable that AI cannot compete with human intelligence in the field of HTA reports, it nevertheless has the following remarkable practical advantage: ChatGPT can produce the text of a preliminary report in under five minutes, whereas a human would need at least half a day to do the same. Of course, it makes little sense to pit humans and AI against each other, but a logical approach would be to start with AI and then refine the report with the human intervention of experts in the specific area.

Finally, it should be remembered that AI learns from experience, so if any critical issues arise during the project, it is hoped that it will improve as it progresses.

This short editorial concludes with a section on how to use the AI-guided tool. This section includes five appendices and can be downloaded from Preprint 1, identified as Reference (1). The five appendices, whose Italian translation can be found in the Supplementary material, are as follows:

- APPENDIX 1: Detailed description of instructions for generating your own mini-HTA report on a MD chosen independently for local needs.
- APPENDIX 2: Example of how to compile basic information on the artificial iris device, taken as an example of the application of the AI-based system presented in this project.
- APPENDIX 3: Display of the "raw and perfectible" mini-HTA report on the MD in question, as generated by CHATGPT using the model ("matrice.docx" file) for the Tuscany Region.
- APPENDIX 4: Display of the mini-report relating to the MD in question, which the Tuscany Region has approved with a specific decree, containing the improvements, corrections and additions that the HTA professionals of the Tuscany Region have introduced based on the 'raw and perfectible' mini-report shown in Appendix 6.
- APPENDIX 5: Instructions for performing a "one-off" installation of the files necessary for the project to function on your computer.

These five Appendices explain how to operate the AI-guided tool with the aim of producing a mini-report in Italian that adheres to the format used in the Tuscany region of Italy. Similarly, Preprint 2 (2) includes a different version of the AI-guided tool that generates a mini-report in Italian with an unspecified format. Therefore, it does not adhere to the typical HTA format used in Tuscany; the objective of the five Appendices remains unchanged.

The fact that this editorial refers to material written in Italian raises an unavoidable language issue in a journal such as Global and Regional HTA. In the field of applying HTA to MDs, the HTA Unit of the Tuscany region has addressed this issue by publishing its mini-HTA reports (currently more than 100) in both Italian and English on the regional website, which is freely available to all (3). However, having completed this preliminary experience and generated a certain number of AI-guided mini-HTA reports, we plan to publish another preprint (3) entirely in English to promote the application of this AI-guided tool outside Italy.

To perform a preliminary evaluation of the performance of this AI-guided tool, we suggest comparing the preliminary AI-guided mini-report generated automatically (1) with the final report officially approved by the Tuscany region that has been published on the Internet (4).

Between October and November 2025, our regional HTA centre (which is responsible for the regional approval of all new Class IIB or III devices) extended the preliminary experience outlined in the initial version of the manuscript. In particular, seven new devices were assessed during this period [see regional decree no. 27042 of 23 December 2025 (5)]. For four of these devices (namely, Brain Access System, Clicav, Versacross and Victo), the first version of the rapid HTA report was generated using the ChatGPT procedure described herein.

The main characteristics of these four MDs are the following:

- Brain Access System (ViewSite Brain Access System, VBAS): A transparent, tubular brain retractor/working channel that creates a minimally disruptive corridor to deep intracranial (and spine) targets while maintaining visualization for microsurgical/endoscopic techniques; used to access and treat deep brain/spinal lesions during neurosurgery (manufacturer: Vycor Medical, Inc.)
- Clicav (Click'a V Plus™): A non-absorbable polymer ligation clip system (with compatible applicators, including articulating options) designed to clamp/ligate vessels or tubular tissue structures to achieve hemostasis and secure closure in open or minimally invasive surgery (e.g., laparoscopic oncologic procedures). (manufacturer: GRENA LTD).
- Versacross (VersaCross™ Steerable Access Solution / transseptal RF system): A steerable transseptal access kit that uses radiofrequency-assisted technology to facilitate controlled crossing of the interatrial septum, enabling left atrial access for catheter-based cardiac procedures, commonly electrophysiology/left-sided interventions (manufacturer: Baylis Medical Company Inc., distributed/supplied in some markets by Boston Scientific).
- Victo (VICTO® adjustable artificial urinary sphincter): An implantable, adjustable artificial urinary sphincter system that restores urethral closure to treat male stress urinary incontinence, particularly due to intrinsic sphincter deficiency such as post-prostatectomy incontinence (manufacturer: Promedon S.A.)

Overall, the performance of this automated generation was satisfactory, but -as expected- a subsequent human intervention was needed in all 4 cases. In particular, the section that most frequently required correction or additions to generate the final HTA report (5) was the table extracted from PubMed and containing the main clinical studies on the device.

In conclusion, a growing body of research is examining the potential applications of LLMs in regulatory science. Numerous authoritative papers on this topic have recently been published (6), confirming the rapid and substantial developments in this area. Although the present article focuses on a very specific issue, it has the potential to contribute to these developments.

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