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Recommendations for Applying Health Technology Assessment

Table of Contents

Introduction

The rising costs of healthcare services, rapid development of new technologies, and the need for rational use of resources have led to the emergence of health technology assessment (HTA).

HTA provides a summary of information on the medical, economic, social, and ethical issues related to the use of health technology to help decision makers better understand their effects. Its evolution and institutionalization over the years have laid the foundation for the systematic and rational HTA that is used today worldwide.

The inconsistent approach to HTA among EU member states, combined with rising healthcare costs and the growing number of new technologies, has created a need for standardization and efficient use of resources through joint assessments. To address this, a network of national agencies and institutions for HTA from European countries (EUnetHTA) was established, which has expanded its activities over the years through various joint actions to improve the HTA methodology and approach.

Having acquired basic resources and experience, EUnetHTA has become an important player in shaping HTA policy in Europe, and its work has been crucial for the development and implementation of the EU HTA Regulation[1] (hereinafter referred to as the Regulation) which was adopted in 2021.

The Regulation represents a key step towards the standardization and unification of assessment processes in the EU, ensuring a consistent approach to innovation and safety. By establishing a Coordination Group and a stakeholder network, the Regulation provides a transparent framework for the involvement of patients and experts, with the aim of improving the availability of innovative technologies and ensuring the optimization of resources. Additionally, the idea is to reduce duplication of efforts among national HTA authorities, facilitate business, and ensure long-term sustainability of cooperation through joint clinical assessments and scientific consultations.

The new EU HTA framework includes joint clinical assessments, joint scientific consultations, identification of new health technologies, and voluntary cooperation.

The new process is expected to lead to faster decisions on introducing innovative technologies into healthcare systems and to improve outcomes for patients.

Current State – Shortcomings and Challenges

Shortcomings of the process of including medicinal products in the CHIF reimbursement list

In Croatia, the Agency for Quality and Accreditation in Health Care and Social Welfare was once responsible for HTA, but in practice, a comprehensive assessment was never conducted, only an assessment based on available data from clinical studies, and for a very small number of medicinal products exclusively at the request of the Croatian Health Insurance Fund (CHIF). With the adoption of the Quality of Health Care Act, the Agency was merged with the Ministry of Health at the beginning of 2019, which took over all its tasks.

Currently, conducting HTA is not mandatory in the process of including medicinal products in the CHIF reimbursement list. Article 16 of the *Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund and the method for determining the prices of medicinal products reimbursed by the Croatian Health Insurance Fund and the method of reporting* (hereinafter: the Ordinance) stipulates that the application for the inclusion of a medicinal product in the CHIF reimbursement list may be accompanied by HTA of the competent authority, if any.

Even though the process of including medicinal products in the reimbursement list and the list of particularly expensive medicinal products of the CHIF is defined in detail by the Ordinance, certain

[1] Regulation (EU) 2021/2282 on health technology assessment (HTAR)

shortcomings have been observed in practice, which makes the process time-consuming. In the following text, we would like to point out the ways the negotiation process can be improved:

- One of the criteria for including a medicinal product in the CHIF reimbursement list, according to the Ordinance, is the number of EU member states in which the medicine has been placed on the market and the number of EU member states in which the medicine is financed by a national health insurance provider. However, the Ordinance does not specify a minimum number of countries. In practice, the CHIF often rejects applications for the inclusion of a medicinal product in the reimbursement list with an explanation that the medicinal product is not included in the reimbursement lists in a sufficient number of countries. This practice is inconsistent and has no basis in the Ordinance. It does not take into account the specificity of individual diseases, especially rare ones, which may have different incidences in different EU countries, as well as different financing mechanisms. The consequence of this is an unjustified delay in the availability of new medicinal products and discrimination against patients in Croatia compared to other EU countries.

- The negotiation process is often not even opened, i.e., the marketing authorization holder's application is rejected "due to an unacceptably high price" and "because the excessively high price is not justified by clinical effectiveness" without inviting the MAH to negotiate the price and the proportion of funding of the medicinal product through a special contract. This practice is also inconsistent and has no basis in the Ordinance because there are no specific parameters/amounts that define a "high price". MAHs must then resubmit extensive documentation with the application for inclusion in the reimbursement list and the list of particularly expensive medicinal products and pay the fee again. Once the negotiation process has begun, each step of the negotiations, i.e., each amendment to the application, is reconsidered at the first following monthly sessions of the CHIF's Committee for Medicinal Products (hereinafter: Committee), which further prolongs the process. The process for including medicinal products in the list of particularly expensive medicinal products consequently takes 12-18 months, which is significantly longer than the average in more advanced EU healthcare systems (6-9 months) and is in contradiction with the provisions of Article 29 of the Ordinance, which prescribes a 90-day deadline for the CHIF to make a decision on submitted applications for inclusion in the reimbursement lists. Furthermore, although the Ordinance requires an assessment of the impact on the CHIF's overall budget when including medicinal products in the reimbursement list and the list of particularly expensive medicinal products, in practice, the CHIF focuses solely on the impact on the medicinal products budget, disregarding potential indirect savings, such as those resulting from reduced hospitalizations, fewer sick leaves, or decreased need for additional diagnostic tests. In addition, the study of the impact on the CHIF's budget, in accordance with Article 18 of the Ordinance, is prepared for a period of three years, which is an insufficient timeframe for proving the effects of the consequences of some chronic diseases (for example, complications of diabetes, hypertension, osteoporosis, etc.).

- The Committee's sessions are not public, and there is currently no possibility of reviewing the minutes of the session at which the MAH's application has been considered, nor is there a more detailed written analysis outlining the Committee's conclusion that could enable the CHIF to initiate negotiations for each application. This leads to a lack of transparency in communication between the Committee and the MAH, and a more imbalanced negotiation process.

- There is no accelerated process for including in the reimbursement list and the list of particularly expensive medicinal products those medicinal products that bring direct savings or have a neutral impact on the CHIF's budget, or medicinal products for which there is a high unmet medical need.

- When considering applications for inclusion in the reimbursement list and the list of particularly expensive medicinal products, the CHIF focuses primarily on the impact of the medicinal product on the CHIF's budget, even though the Ordinance stipulates that the value of innovative medicinal products and the benefits for patients must also be taken into account.

According to the ***EFPIA Patients W.A.I.T. Indicator 2023 Survey***[2], published in 6/2024 for the period **2019-2022**, Croatia ranks among countries with lower overall availability of medicinal products (although it is one of 4 countries that do not fully meet the criteria for data required for the analysis, along with Cyprus, Bosnia and Herzegovina, and North Macedonia). This means that Croatian patients receive their medicinal products after a long wait and in significantly smaller numbers compared to the EU and neighboring countries.

Table 1: Number of available medicinal products in Croatia and Slovenia 2019-2022

Number of available medicinal products in 2019-2022	**All 167**	**Oncological 48**	**Rare diseases 63**	**Non-oncological 47**	**Combination therapies 13**
Croatia	40	14	9	5	4
Slovenia	70	24	23	17	6

What is worrying is that, compared to the period **from 2018 to 2021** (according to the same survey), Croatia is showing a negative trend.

Table 2: Number of available medicinal products in Croatia and Slovenia in 2018-2021

Number of available medicinal products 2018-2021	**All 168**	**Oncological 46**	**Rare diseases 61**	**Non-oncological 44**	**Combination therapies 22**
Croatia	46	16	10	6	4
Slovenia	72	21	22	15	10

In addition to the number of innovative medicinal products becoming available to patients in Croatia, it is particularly important to consider the time it takes for new therapy options to be incorporated into clinical practice. Bearing in mind that new therapy options generally improve treatment outcomes, improvements in the process of inclusion in the reimbursement list and the list of particularly expensive medicinal products would provide better treatment for all those who need it.

Challenges of the availability of innovative medical devices

As with medicinal products, comprehensive HTA has never been conducted for medical devices in Croatia. There were only assessments based on available clinical data for a very small number of interventions, exclusively at the request of the CHIF. Such procedures are mostly limited to checking formal criteria and prices, without a comprehensive analysis of clinical effectiveness or cost-effectiveness of a particular technology. For example, in the decision-making process on new therapies, there have been cases where applications have been rejected with an explanation that the product is not yet sufficiently present on the lists of other EU countries – a practice that is not formally established in regulations.

There is currently no legal obligation to conduct HTA when deciding on the introduction of new medical devices into practice or their reimbursement. At the same time, the costs of medical devices are continuously increasing – for example, in recent periods, the purchase prices of many assistive devices have increased by up to 30-40%. In addition, medical device manufacturers are not included in the assessment process, which may result in important information about the true value and

[2] EFPIA Patients W.A.I.T. Indicator 2023 Survey

impact of new technology remaining unused. The absence of such a multidisciplinary approach in Croatia currently makes it difficult to assess the true value of medical devices and may delay the introduction of innovations that would benefit patients. This absence of a standardized methodology results in inconsistent and non-transparent decisions, highlighting the need for clearer guidelines and objective assessment criteria.

What does the new EU HTA framework bring?

The Regulation brings about the harmonization of HTA through common standards and methods among member states, thus ensuring consistency and quality. It introduces a mechanism for joint clinical assessments and scientific consultations, reducing duplication of efforts and optimizing resources. It also enhances the participation of patients and experts in the assessment process, increases transparency in decision-making and ensures long-term sustainability of cooperation; all of which contributes to better access to safe and effective health technologies for patients in the EU.

In order to guarantee the highest quality of joint clinical assessments, ensure broad acceptance, and enable pooling of expertise and resources across national competent authorities and other HTA authorities, the process will begin with a limited number of jointly assessed medicinal products. At a later stage, it will expand to include all other medicinal products and certain medical devices belonging to the highest risk classes and class D *in vitro* diagnostic medical devices. From the entry into force of the Regulation, all new oncology medicinal products and advanced therapy medicinal products will be covered in the second phase, followed by all medicines for rare diseases from 2028, and all remaining products from 2030 onward.

A Coordination Group composed of representatives of the member states has been established for the purposes of monitoring the implementation of joint clinical assessments and other joint work covered by the scope of this Regulation.

The new EU HTA framework includes joint clinical assessments, joint scientific consultations, identification of new health technologies, and voluntary cooperation, and for each segment the Coordination Group has established appropriate subgroups.

Obligations and rights of member states

Member states should implement the Regulation by integrating joint clinical assessments (JCA) into their national HTA systems. They should also actively cooperate with EU bodies by participating in joint initiatives and working groups to exchange knowledge and experience.

The HTA Regulation creates a framework for cooperation between member states, ensuring consistency and quality of assessments. Even though they are required to follow certain guidelines, member states have significant flexibility in how they implement these processes.

Member states are responsible for their health policy and the provision of health services, including the allocation of resources, under Article 168(7) of the Treaty on the Functioning of the EU. The Union's action is limited to joint clinical assessments of health technologies, without value judgments, respecting the competence of the member states. These assessments include a scientific analysis of the effects of health technologies according to selected parameters and a consideration of the certainty of the available evidence. The outcome of the assessments does not affect the right of member states to assess the clinical added value or to set prices and reimbursements for health technologies, which remains within their national competence.

Member states may conduct additional clinical analyses of health technologies in addition to the available joint clinical assessment report in order to complement the national assessment process. These analyses may refer to specific patients, comparisons, or health outcomes not covered in the report. If additional information is needed, member states may request data from the entity developing the health technology. The Regulation must not limit the rights of member states to conduct non-clinical assessments of the same technology before, during, or after the publication of the report.

At the very beginning of the implementation of the joint clinical assessment, which begins almost in parallel with the process of medicinal product authorization by the European Medicines Agency, all member states have the opportunity to participate through the process of determining the scope by responding and completing the PICO questionnaire, i.e., submitting information on the patient population, intervention, comparator technology and health outcomes that are relevant to them. The scope of the assessment must be inclusive and reflect the needs of the member states in terms of parameters and information, data, analysis, and other evidence to be submitted by the entity developing the health technology.

The final HTA carried out at a national or regional level for a particular health technology previously assessed at the Union level should be made available to the Coordination Group. Member states should submit information on the national assessment within 30 days of completion, highlighting how they have taken into account the joint clinical assessment reports. Based on this information, the Commission will publish an annual report on the application of these assessments.

In the context of the Regulation, the term "give due consideration" means that the joint clinical assessment report should be part of the documentation of the competent authorities for HTA at a national or regional level. It should be taken into account in any assessment, but the content of the report is not binding. If the report is not available at the time of completion of the national assessment, this should not delay the process, and member states should not request the same information that has already been provided at the EU level. This Regulation reduces the administrative burden for entities developing health technologies.

AmCham recommendations

The current process of including medicinal products in the CHIF reimbursement list

The number of EU member states in which a medicinal product is funded by a national health insurance provider as a criterion for including medicinal products in the reimbursement list of the CHIF should be applied in accordance with the Ordinance, i.e., it should not be used to reject or slow down the application of a MAH, and thus limit the availability of medicinal products for patients in Croatia.

The process could be accelerated by ensuring that the CHIF does not reject applications of MAHs based on arbitrary assessments of the price level, or the impact on the CHIF's budget but rather by opening a negotiation process more quickly with the aim of reaching a mutually acceptable agreement on the price of the medicinal product and the proportion of funding, which will include all aspects of the impact on the healthcare system, including recognition of the value of innovation. We also propose implementing an accelerated procedure for medicinal products that bring direct savings or have a neutral impact on the CHIF's budget, or medicinal products for which there is a high unmet medical need.

In order to increase the transparency of the process, we propose that the conclusions of the Committee be provided to the MAH for review for each application, which would initiate the negotiation procedure more quickly.

- ***AmCham's proposal:***

  Discontinuation of using the number of EU member states in which a medicinal product is funded by a national health insurance provider as a reason to reject the application of the MAH.
  Faster initiation of the negotiation process on the price of the medicinal product and the funding proportion.
  Implementation of an accelerated procedure for medicinal products that bring direct savings, have a neutral impact on the CHIF's budget, or for which there is a high unmet medical need.
  Providing the Committee's conclusions for review to the MAH for each application.

Joint clinical assessment

The result of a joint clinical assessment is a report that includes a summary, but does not draw conclusions about the clinical added value of the health technology. The report is based on a scientific analysis, while member states should draw conclusions on clinical value at a national level, taking into account the specific healthcare context and the relevance of the included analyses.

It is the obligation of the member states to take the aforementioned report into account during the national assessment. According to the currently applicable Ordinance, the national assessment is carried out by a Committee in which various specialties are represented, and if necessary, the Committee may request an additional opinion (from the professional association of the Croatian Medical Association, the reference center of the ministry in charge of the healthcare system, the Agency for Medicinal Products and Medical Devices, an assessment by a competent authority for the assessment of health technologies, another professional association, or a specialist in a specific field).

Accordingly, in order not to prolong the process further, we believe that no major changes are necessary in the national process when it comes to reaching a conclusion on the joint clinical assessment report, that is, it can be carried out in a quality manner by the above-mentioned stakeholders, but with the mandatory involvement of a specialist in the specific filed, which is already defined as a possibility in the existing Ordinance.

We also believe that good practice from countries that have already implemented HTA should be applied, particularly regarding process transparency for all stakeholders, especially MAHs who have the opportunity to review and participate in the assessment process.

What must be emphasized is the prescribed deadline of 90 days for the Committee to issue an opinion, or 30 days for submitting an additional opinion, which should now, thanks to the joint clinical assessment report, be more achievable.

- ***AmCham's proposal:***

  Keeping the existing framework in which the Committee for Medicinal Products is responsible for reaching a conclusion on the joint clinical assessment report, with the mandatory involvement of specialists from the specific field.
  Possibility of reviewing and participating in the assessment process for marketing authorization holders in line with the good practices of other member states.
  Respecting the prescribed deadlines for issuing opinions, which should now be more easily achievable thanks to the availability of joint clinical assessment.

PICO questionnaire

Since the Committee is conducting a national assessment, we believe that it should also be included in the monitoring of the process of completing the PICO questionnaire, i.e., defining parameters for a joint clinical assessment that are relevant for Croatia, which would be prepared by the professional association of the Croatian Medical Association. We also believe that MAHs should be able to provide their suggestions and expert information, which is already established in some countries (e.g., in Austria and Poland). We also expect that MAHs will be informed about the final PICO which will be sent to the Coordination Group.

- ***AmCham's proposal:***

  Active participation of the Committee for Medicinal Products in monitoring the process of completing the PICO questionnaire and defining parameters relevant to Croatia.
  Possibility for MAHs to provide suggestions and expert information.
  Ensuring that MAHs are informed about the final PICO that will be sent to the Coordination Group.

Opportunity to improve the availability of medical devices

HTA can also help in addressing the above-mentioned challenges in the availability of innovative medical devices. In other words, applying the aforementioned health assessment mechanisms can support the Croatian healthcare system in determining, based on evidence, which technologies offer

justified value for money through improved treatment outcomes and increased healthcare system efficiency.

This includes the gradual implementation of joint clinical assessments for high-risk medical devices, in accordance with the phased implementation plan of the Regulation. It is necessary to establish or designate an independent and multidisciplinary body that will conduct the national assessment and be responsible for drawing up a conclusion on the joint clinical assessment report for medical devices. It is essential that this body has clear mandates, secured financial and human resources, and access to international cooperation to exchange knowledge and best practices.

We reiterate that good practice from countries that have already implemented HTA should be applied, particularly regarding process transparency for all stakeholders, especially manufacturers of medical devices who have the opportunity to review and participate in the assessment process.

The timely integration of these standards into the national system will ensure that Croatian patients gain faster access to safe and effective innovations while preserving the financial sustainability of the system. In the long term, this means faster access to more effective products for patients, while making optimal use of available resources and encouraging innovations that truly contribute to better care.

- ***AmCham's proposal:***

  Gradual implementation of a joint clinical assessment for high-risk medical devices.
  Designation of a body responsible for the implementation of the national assessment and the conclusion of the joint clinical assessment report for medical devices.
  The ability to provide suggestions and expert information to manufacturers of medical devices.

In conclusion, we believe that the implementation of the Regulation should lead to faster decisions on the introduction of innovative technologies into the Croatian healthcare system through more intensive cooperation with MAHs and manufacturers of medical devices, with the aim of improving treatment outcomes in Croatia. However, even before the implementation of the Regulation, there is a possibility of accelerating the current process of including medicinal products in the CHIF reimbursement list via the above-mentioned recommendations.

The current process of including medicinal products in the CHIF reimbursement list

- Discontinuation of using the number of EU member states in which a medicinal product is funded by a national health insurance provider as a reason to reject the application of the MAH.
- Faster initiation of the negotiation process on the price of the medicinal product and the funding proportion.
- Implementation of an accelerated procedure for medicinal products that bring direct savings, have a neutral impact on the CHIF's budget, or for which there is a high unmet medical need.
- Providing the Committee's conclusions for review to the MAH for each application.

Joint clinical assessment

- Keeping the existing framework in which the Committee for Medicinal Products is responsible for reaching a conclusion on the joint clinical assessment report, with the mandatory involvement of specialists from the specific field.
- Possibility of reviewing and participating in the assessment process for marketing authorization holders in line with the good practices of other member states.
- Respecting the prescribed deadlines for issuing opinions, which should now be more easily achievable thanks to the availability of joint clinical assessment.

PICO questionnaire

- Active participation of the Committee for Medicinal Products in monitoring the process of completing the PICO questionnaire and defining parameters relevant to Croatia.
- Possibility for MAHs to provide suggestions and expert information.
- Ensuring that MAHs are informed about the final PICO that will be sent to the Coordination Group.

Opportunity to improve the availability of medical devices

- Gradual implementation of a joint clinical assessment for high-risk medical devices.
- Designation of a body responsible for the implementation of the national assessment and the conclusion of the joint clinical assessment report for medical devices.
- The ability to provide suggestions and expert information to manufacturers of medical devices

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