

The proposed European Commission Regulation on HTA: a golden opportunity for patients and health budgets

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THE PROPOSED EUROPEAN COMMISSION REGULATION ON HTA: A GOLDEN OPPORTUNITY FOR PATIENTS AND HEALTH BUDGETS

On June 22, EU Health Ministers met in Luxembourg for the concluding EPSCO Council under the Bulgarian Presidency of the EU. The agenda included tough discussions of the European Commission's proposal for a Regulation on Health Technology Assessment (HTA), amending Directive 2011/24/EU. The fact that the item was put on the Ministers' agenda took many by surprise since national delegations have had only two Council Working Party meetings to begin to discuss the text. The European Parliament has been working arduously, sticking to the timetable and defending the core of what the Commission put forward on January 31, aiming to adopt its position by the October plenary session.

Ministers were invited to answer a very straightforward question from the Bulgarian Presidency (which has not hidden its strong dissatisfaction with aspects of the Commission initiative) on whether they support or oppose the core principle of the proposal regarding the mandatory participation in the joint clinical assessments and most importantly, the mandatory national uptake of the conclusions of these assessments. Several Ministers expressed reservations as to the mandatory uptake of the joint clinical assessments.

Why are governments suspicious of the proposal?

This mandatory-mandatory combination has

polarized the conversation between Member States. Numerous governments consider this to be overstepping into sensitive national competences. In particular, they are concerned that a mandatory European HTA system will tie their hands and restrict their decision-making power on which medicines should or should not be reimbursed. The concern is that if a product gets a European HTA green light, it will be much more difficult for a national government to decline its reimbursement. Some Health Ministers wish to keep pricing and reimbursement decisions as close as possible. At the same time, others worry that the new EU HTA system will be vulnerable to capture by pharmaceutical companies who have long despised HTA as the fourth, hard-to-predict, hurdle (in addition to proving good quality, efficacy and safety) which stands between them and national coverage decisions.

Another crucial point, not raised in the EPSCO discussions, is that a new EU-wide HTA framework which is institutionalised and quite predictable would signal a step towards decentralising power, consequently reducing individual national politicians' leverage. Where insufficient checks and balances are in place, this not only gives them more power and influence but also opens the door to possible corruption. The allegations around the recent Novartis scandal in Greece show that this isn't just a theoretical risk.



HTA is important as a tool for governments to identify to what extent a new medicinal product is better than currently available treatments. However, another reality which needs to be openly talked about today, is that in certain cases, HTA can be exploited as a way for governments to win time against reimbursing more costly medicines that do have important added therapeutic value. It is important that HTA is not politically deployed as a mechanism to procrastinate on taking these difficult decisions.

Health Technology Assessment, the issue nobody used to talk about

The recently proposed EU Regulation has put HTA at the centre of a political discussion on the broader question of access to medicines and their affordability which has moved to the top of the European agenda in recent years. Unsurprisingly, during last week's EPSCO, quite a few delegations linked HTA with access and affordability and expressed their concerns over the budgetary impact of some new medicines. HTA is undeniably an integral part of this political discussion while simultaneously being a technical-scientific evaluation.

HTA at its birth was heavily promoted by the pharmaceutical companies themselves. They wanted HTA to justify the very high prices of some new drugs. Nonetheless, as they have continued to hike their prices up in recent years, the project has come back to haunt them. In the face of the paralysing budget impact of numerous drugs in oncology, rare diseases, Hepatitis C (HCV), HIV and others, more and more governments began

to establish new or reinforce existing HTA agencies, finding that most of these new drugs didn't measure up to their price tags. IQWiG, the German HTA agency was strengthened in 2011, while Denmark set up its own national HTA body in January last year with the explicit objective of cost-containment and bolstering the Danish government's position in their negotiations with pharmaceutical companies. Greece is now pursuing a similar path. HTA has thus gained prominence in recent years as European governments struggle to cope with the high prices charged and look for tools to use as gatekeepers.

HTA: a powerful ally of patients and healthcare systems

The high prices of certain drugs aside, Health Technology Assessment is a powerful ally of patients and health care systems. If used properly, HTA serves patients' needs and interests, making the case for information and evidence which show that the new medicines offer meaningful innovation rather than imitation – and give a vital signal to steer medical R&D in that direction. HTA agencies are often falsely held responsible for the rationing of treatments, accused of stalling access or cherry-picking the data in order to help payers (statutory social insurance systems) to delay or avoid the reimbursement of certain drugs. In reality, any rationing is a direct consequence of aggressive pricing strategies pursued by pharmaceutical companies. The recent proposal is the right way to dispel this belief.





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Getting it right: EPHA recommendations on how to improve the Commission proposal

EPHA has made five recommendations on the Commission proposal (highlighted).

1. Complete data for informed, evidence-based decisions

The proposed Regulation offers a golden opportunity to ensure that HTA bodies have access to as much data and evidence as possible. Instead of blaming HTA agencies, we should hold drug and medical device developers accountable, and force them to submit dossiers which are as complete as possible from the very start, with the possibility to reassess and update the assessments with additional evidence as it becomes available while guaranteeing the maximum degree of transparency. Strict timelines for the completion of additional studies, and sanctions in case of non-compliance with the aforementioned requirements, should also be included in the text.

2. Transparent, reliable assessments will build trust in the new EU HTA system

The EC proposal needs to be improved to ensure full transparency of all data without any redaction, e.g. manufacturer submission in addition to HTA report, which is not at present foreseen in the EC proposal. In this way, all stakeholders are able to understand and possibly challenge any HTA report and the HTA authorities cannot be accused of manipulating the evidence. On the contrary, a solid – openly

published - evidence base will lead to more reliable assessments and will build trust in the new EU system.

Transparency is just as critical when it comes to the dealings between the pharmaceutical companies and HTA agencies in the context of the preparation of the clinical assessment. Article 6(8) should be amended to prevent interference by the company whose product is being assessed before the publication of the joint assessment. The proposed regulation rather needs to ensure that the company is only consulted after the clinical assessment is completed to avoid undue influence from the outset.

Light should also be shed on the provision of scientific advice granted through the joint scientific consultation process, while always keeping in mind that the EMA and HTA bodies have different remits.

Inserting such pro-patient, pro-transparency provisions in the text will help alleviate some governments' concerns that this new proposal risks increasing the power of the pharmaceutical and medtech companies throughout the process, potentially skewing the pricing and reimbursement negotiations. Indeed, such transparency provisions are needed to redress the balance for governments and payers.

In order to increase the chances of reaching agreement on the proposal, EU capitals need to be convinced that the future HTA system will act as a gatekeeper, as well as a door-opener for genuine, public health needs-driven therapeutic advance. There are vast economic





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interests at stake both for the pharmaceutical industry and national health budgets. Therefore, the proposal should aim to set up a robust and independent HTA system which is perceived as credible by all stakeholders. In other words, the proposal needs to have teeth.

3. Strengthening national capacity for a truly EU-wide HTA system

Thanks to the Commission initiative, Member States have a unique opportunity to enhance the HTA system in Europe and tackle its current shortcomings including the disappointing performance of EUnetHTA. How will this be accomplished? The EU system should complement and stimulate a strengthening of national capacity. Many national HTA agencies number only a few staff members and have very limited budgets. Governments need to prioritise the reinforcement of the relevant national authorities (medicines, pricing and reimbursement, competent authorities, HTA etc.) as a way to cope with the imbalances in market power and information asymmetry between medicines/medtech buyers and sellers. We should not forget that government officials meet and negotiate with globally acting pharmaceutical companies that can mobilise resources and expertise, potentially in excess of resources available to the public authorities.

4. A credible new EU HTA system resistant to regulatory capture

It is very welcome that the latest Commission proposal on HTA has triggered a discussion about the risks of regulatory capture by the

pharmaceutical and medtech industries. The prospect of depending on industry fees for the financing of the future EU HTA system underlines the need for unfettered independence. At present, most major HTA agencies in the EU, with the exception of the UK National Institute for Health and Care Excellence, do not receive any fees from pharmaceutical companies, for good reason. It is widely perceived that industry fees could undermine or jeopardise the independence of these agencies. However, the absence of industry fees is no guarantee against regulatory capture – further safeguards are needed as regulatory capture is multi-faceted.

It is therefore critical for the credibility of the new EU system to ensure its independence and integrity while providing the necessary resources for capacity-building at national level. Robust policies on conflicts of interest of organisations and individuals involved should be a legal requirement from the outset.

5. Independent from the EMA: Good fences make good neighbors

When developing a new piece of legislation, the challenge for legislators is to think long term and in this case, at least 5-8 years ahead. Currently, the proposal foresees the creation of a central secretariat hosted by the European Commission (with no industry fees) for the initial period of six years following the Regulation's entry into force. However, the proposal does not define what should happen to the secretariat after the end of the transitional period – but suggests a review before either





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moving it to an existing Commission agency or establishing a new agency. Although this may not be a question to answer right now, it is important for legislators to consider the possible future symbiosis between the new EU-wide HTA system and the European Medicines Agency (EMA).

It is hard to predict what the political appetite will be for the establishment of an independent HTA EU agency following the end of the transitional period but allowing it to become a subdivision of the EMA should be avoided at all costs. An alignment of criteria or the evidentiary requirements is welcome but a possible absorption of HTA by the EMA would lead to an excessive concentration of power at the EMA. Such a scenario would likely undercut the HTA's potential in mitigating problems caused by the EMA and its approvals. Today, numerous HTA bodies, pricing and reimbursement authorities as well as social insurance schemes (payers, sickness funds) are concerned about an increasing number of medicines being approved by the EMA based on premature data or a weak evidence base. HTA can indeed serve as the answer to this weak evidence-high prices conundrum as long as HTA itself does not become subordinated to the EMA.

Nevertheless, it would be beneficial if the EMA could take on board more of the HTA authorities' demands for more stringent evidentiary requirements such as more comparative trials. This would offer companies clarity and increased predictability on the questions asked both by the EMA and HTA process at an earlier stage. The need for comparative trials

against the best standard therapies needs to be enshrined in the proposed Regulation. On a similar note, the Regulation has to explicitly stipulate that the assessments are based on the international criteria of evidence-based medicine.

Next steps

Contrary to fears, the Ministerial debate of 22 June 2018 was not the kiss of death for the HTA proposal but a fresh start for the negotiations. The real journey for the proposed Regulation starts now under the new Austrian Presidency of the EU. The Austrian Government has pledged to advance the negotiations by putting HTA on the agenda of numerous Council Working Parties until the end of their Presidency. This does not mean that the "mandatory-mandatory" principle will not be diluted. Following the EPSCO discussion, the Commission will doubtlessly have to meet Member States halfway as many of them have repeatedly called for flexibility to be built into the system. Practically, this means that the mandatory application of assessment results and the prohibition of own assessments will be modified accordingly in the coming months. In spite of the Austrian push, it is unlikely that the negotiations on this file will be concluded by the end of the European Parliament's current term. One thing is certain, nobody in the Council currently wishes to "kill" the proposal completely. As [previously¹](#) discussed, the HTA negotiation is not taking place in a policy vacuum and will be used as a trade-off between the parallel ongoing discussions on other access to medicines-related issues

1. Natsis, Y. (2018) The top 5 issues in EU medicines policy for 2018. *In: Medicine Access @ Point of Care*. Vol. 2. <http://journals.sagepub.com/doi/full/10.1177/2399202618774510>



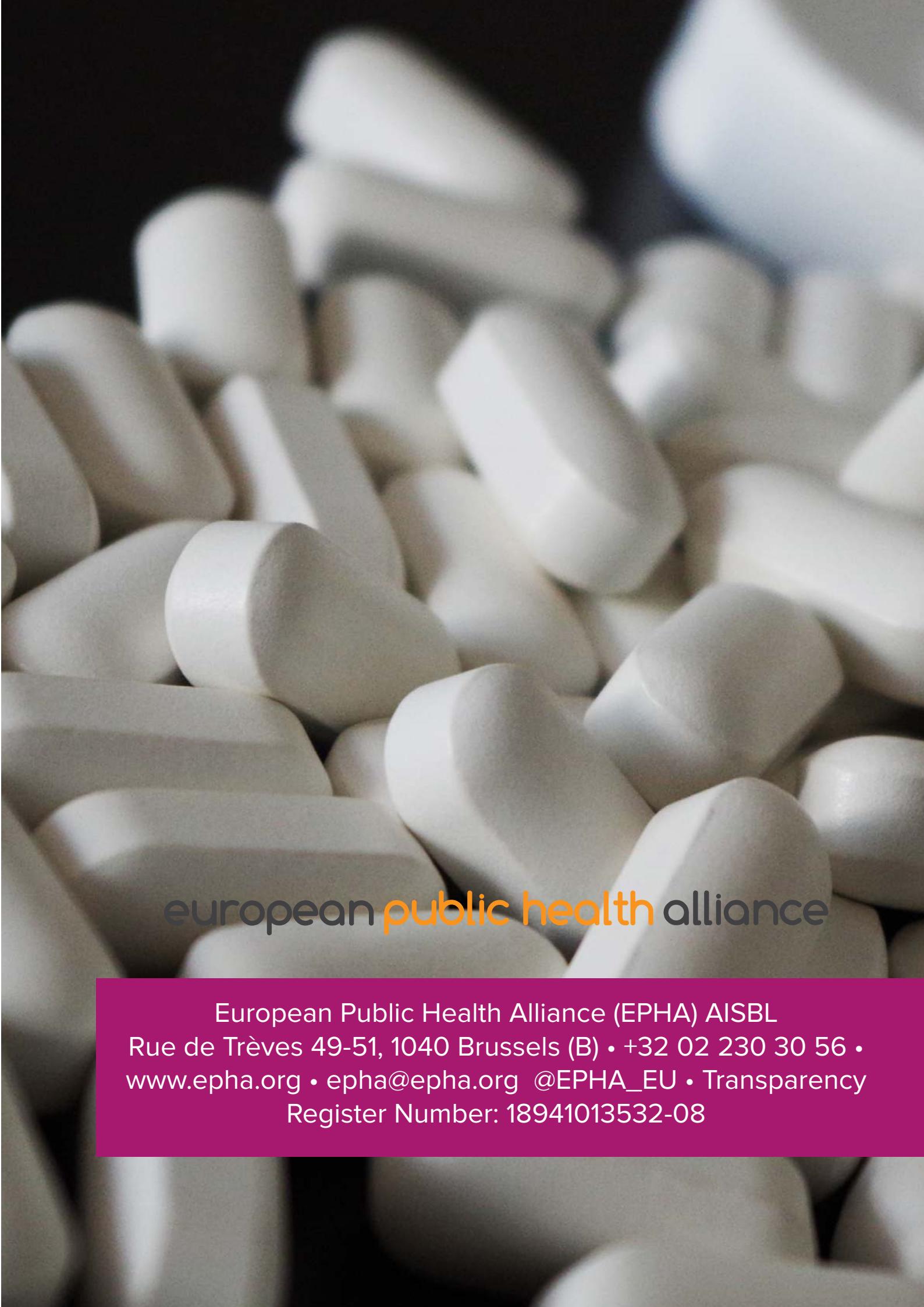
and policies, some of which are not yet on the horizon.

Overall, although no-one is truly opposed to European collaboration in this field, there is considerable anxiety from all sides over the unknown future landscape. Payers, pharmaceutical companies and health ministries are trying to navigate unchartered waters. Both payers and health ministries do not want to see their freedom over reimbursement choices limited in any way due to a strong or weak EU-wide HTA system. Pharmaceutical companies are relatively happy with the status quo as they are used to doing business with the current fragmented European HTA landscape. Over the years, they have built up their collaboration with key HTA players in Europe, they have become familiar with national players and their specificities and know what to expect in every Member State - compared to an unknown and consequently, very uncertain EU HTA system. The fact that these discussions are taking place in the midst of growing and widespread concerns over

the rising prices of medicines is only adding to the industry's worries over how solid a gatekeeper the new HTA system will prove to be. On the other hand, the prospect of an EU-wide HTA system similar to the EMA excites pharmaceutical companies.

The discussions at the European Parliament have been relatively smooth with no major standoffs. This will not be the case in the Council. Despite the very public debate and often emotional statements by government officials and others since the launch of the proposal a few months ago, Member States have yet to show their red lines and the divisions and alliances in the Council are still being shaped. The pharmaceutical companies on the other hand have not yet mobilised their lobbying resources to the fullest as they are on standby waiting for the negotiations to get underway in the Council. One thing is certain, the text as well as Member States' red lines will continue to evolve and will change considerably beyond the end of the Austrian Presidency in December. ■





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