DISCUSSION PAPER

HEALTH ACTION INTERNATIONAL

Introduction

As 2019 drew to close, Health Action International (HAI), like many of its peers, looked back on a year of minimal progress on the issue of Health Technology Assessment (HTA) reform and challenged 2020 to be the year that would break the impasse. Instead the HTA file was one of many to be put on the backburner whilst COVID-19 wreaked havoc on populations, economies and healthcare systems, redirecting Member States' resources and redefining the political agenda. This delay is concerning to HAI: we believe joint HTA is an important development in access to medicines and believe that increased participation will encourage transparency and the sharing of information and expertise across the continent. In fact, the COVID-19 crisis itself highlighted the place for joint HTA in handling cross-border health threats and how data sharing is critical to the expeditious research and development (R&D) needed to meet urgent challenges–something that the World Health Organisation's COVID-19 Technology Access Pool is also seeking to champion. As a result, one year on from our expression of hope that 2020 would bring progress, we were pleasantly surprised to see the German Presidency of the European Union (EU) ending its term in a flurry of action.

Progress on HTA 2011-2019[1]

The first step towards EU-wide collaboration on HTA was taken in 2011 with the introduction of the HTA Network in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.[2] The HTA Network is supported on scientific and technical issues by the European Network for Health Technology Assessment (EUnetHTA). This initiative originally was due to run until May 2020 but its mandate was extended by one year due to COVID-19. Voluntary use of the HTA Network was not widespread, however, which led the European Commission to take a more formal approach.

In January 2018 the European Commission adopted a proposal for a regulation on joint HTA.[3] The regulation aims to create sustainable cooperation and identifies four components that should be carried out collaboratively at the EU level: joint scientific consultations, joint identification of emerging health technologies ('horizon scanning'), joint clinical assessments (which the regulation makes mandatory), and voluntary cooperation on other areas of HTA. In September 2018 the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament adopted the proposal with a key

[1] Thanks go to Simon Geukes, Health Action International intern in the European Projects Team, for his research on HTA which involved interviewing stakeholders working on HTA policy in patient and consumer organisations, national HTA organisations and in academia and formed his thesis 'The perspectives of stakeholders on EU regulation on health technology assessment' undertaken as part of his MSc Science in Society at the Vrije Universiteit, Amsterdam.

[2] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, *European Commission*, 9 March 2011 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024

[3] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU, *European Commission*, 31 January 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018PC0051

amendment allowing Member States to top up the mandatory joint clinical assessments with additional clinical evidence and analyses. The report was adopted in February 2019, ending its First Reading. The report went to the Council of the EU where reactions were mixed. While all members indicated they were in favour of enhanced European cooperation, issues were raised in working groups throughout 2018. These issues were predominantly around quality and timeliness of joint clinical assessment outcomes, and the consequences of non-compliance. The Health Ministries of six Member States expressed deep concerns over the mandatory uptake element and in particular mandatory joint clinical assessments (JCAs) which are seen as a potential infringement on Member States' right to manage their own healthcare systems. These concerns led to a debate amongst EU Ministers of Health in June 2018 concerning mandatory versus voluntary uptake; the Austrian Presidency of the Council found there to be a preference for voluntary uptake and informed the Council of the European Union of this in December 2018.

Romania held the Council Presidency in the first half of 2019 and their June progress report indicated that they had focused on joint scientific consultations and horizon scanning, neither of which impinged on the real debate over mandatory JCAs.[4] Such was the lack of progress on this area that the European Parliament's rapporteur on the HTA file, Tiemo Wölken (Soc. Dem., Germany), tried to draw a 'red line' on the issue by stating that the Parliament would only agree to a compromise on HTA if the JCAs remained mandatory.

By the end of 2019, the HTA file had already been on the desks of two Council Presidencies, and the lack of action meant that we were not able to see whether our concerns with the original proposal had been addressed, namely that:

- Member States are allowed to participate in joint assessments at a pace that suits them and their available resources;
- Flexibility to carry out additional assessments to meet a State's specific public health needs where necessary;
- A commitment to enforce conflict of interest policies is made; and,
- The high standards of assessments currently found across the EU are protected.[5]

Progress in 2020

There was extremely limited progress on HTA over the first six months of 2020 due to the spread of COVID-19. The Council of the EU noted that 'experts dealing with HTA in the Member States were actively involved in emergency tasks related to the fight against COVID-19' and, as a result a 'large number of delegations' expressed concerns about participating in further work during the Croatian Presidency (January-June 2020).[6] The Presidency suspended video calls and meetings of the Working Party and instead asked delegations to submit written comments on three sets of documents. In the end, only nine did so wich is perhaps indicative of Member States' lack of resources or lack of political interest. The Presidency did not table any proposals for changes to the text of the HTA Regulation because 'there would not be sufficient time for discussion, and furthermore, due to the ongoing pandemic, delegations would not have equal opportunities to engage in discussions on this important file'.[7]

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[4] Health technology assessment post 2020, *Council of the European Union*. Accessed online 14 December 2020: https://www.consilium.europa.eu/en/policies/health-technology-assessment-post-2020/#

[5] Health Technology Assessments: Will 2020 end the deadlock? *Health Action International* (17 December 2019) https://haiweb.org/health-technology-assessments-2/

[6] Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Presidency Progress report, *Council of the European Union* (15 June 2020) https://data.consilium.europa.eu/doc/document/ST-8737-2020-INIT/en/pdf

[7] Ibid.

In July, Germany took over the Presidency: their stewardship of the Council was widely expected to be the catalyst needed to get the file moving. However, the COVID-19 crisis continued to dominate the second half of the year and the HTA file was not scheduled for discussion by Health Ministers until 2 December.[8] Given the COVID-19 crisis, the meeting was held by videoconference, and the HTA file was relegated to being an 'additional agenda item' in much of the press outpouring surrounding the meeting.[9]

German Health Minister Jen Spahn gave an update in the public session section of the December meeting in which he highlighted the reasons for the delays on the file: the sensitivities around discussions of EU and Member State competencies, sensitivities around pricing and the complex nature of the technical side of the cooperation.[10] He explained that despite the delays due to COVID-19, and crediting the work of the Presidencies before theirs, his team had come up with a new compromise text for the regulation, purportedly taking into account all of the proposals and concerns, and on which they hope to be able to build a consensus. He explained that his compromise text will be handed over to the Portuguese Presidency to take forward. The main positives of the compromise text, according to Minister Spahn, are:

- It strengthens the role of the Member States to make it clear it is a Member State driven process.
- It adds detail to the points about data to clarify that the process should involve sufficient data to allow for EU wide evaluation.
- It explains that the directive will be broadened in a step-by-step fashion in order to not overload Member States, to facilitate information sharing and learnings and to establish the mutual trust that is critical to European cooperation.
- It adds flexibility to allow 'other things that are important' to be assessed alongside HTA, which gives a balance between planning and being flexible.
- It is based not on one legal article of EU founding treaties, but two (articles 114 and 168).

Beyond Minister Spahn's points, the compromise text is promising in that it details a conflict of interest policy, makes a concession to Parliament concerning allowing Member States to undertake additional clinical assessments, and that it outlines a step by step approach, beginning with a small number of JCAs. This final point is in line with the findings of research undertaken for HAI in 2020 by Simon Geukes, which found that mandatory uptake of JCAs is well supported amongst relevant stakeholders, as is the addition of a trial period for Member States to gradually expand their resources and prepare for deeper collaboration.[11] A trial or pilot period would allow Member States to better understand the technical requirements of aligning JCAs, as well as the benefits of effective EU collaboration, in a way that feels more Member State driven. We support its inclusion in the discussion.

However, there remains some room for refinement, particularly around the key issue of mandatory versus voluntary JCAs, of which Minister Spahn made no mention in his update. This was a likely a deliberate political choice given the compromise text repeatedly reinforces the need for JCAs to remain voluntary, and non-binding, arguably undermining the original intention of the regulation in the first place.

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[8] Draft agendas for Council meetings, during the second semester of 2020 (the German Presidency*), Council of the European Union* (30 June 2020) https://www.consilium.europa.eu/media/44868/st09250-en20.pdf

[9] EU Health Ministers discuss integrated European health management and the COVID-19 pandemic, *website of the German Presidency, eu2020.de*. Accessed online on 14 December 2020: https://www.eu2020.de/eu2020-en/news/article/pandemic-spahn-eu-health-ministers/2421178

[10] Video conference of health ministers 2 December 2020, accessed online 14 December 2020 https://video.consilium.europa.eu/event/en/24271

[11] Geukes, S. 'The perspectives of stakeholders on EU regulation on health technology assessment' (July 2020), unpublished thesis via Vrije Universiteit, Amsterdam.

While it is certainly positive to see movement on the file, and the Council has taken into account some of the concerns of national governments around competencies and data, we hope that the mandatory JCAs issue does not derail the debate and that all parties concerned commit to finding a compromise.

The 2 December meeting also provided Stella Kyriakides, European Commissioner for Health and Food Safety, the opportunity to express her support for this renewed momentum on HTA and to pledge her commitment to resolve the stalemate. This is a powerful endorsement from the Commission for progress and gives the clearest indication yet of Kyriakides' position on HTA.

In addition to these Ministerial level meetings, the HTA Network restarted its work in November 2020, and by association the EUnetHTA network has begun to return to normality. The EUnetHTA Forum convened its first meeting of 2020 on 4 December to provide stakeholders, including HAI with an update on progress on the regulation as well as progress in collaboration more generally. Stakeholder engagement has certainly been a victim of the COVID-19 crisis with many stakeholders not having heard from the network in over a year: this has led to a marked lack of scrutiny of processes, even as collaboration efforts stepped up to fight the pandemic. HAI participated in a letter to the board of EUnetHTA Joint Action 3, highlighting the need for formalised stakeholder engagement processes; during the 4 December meeting HAI again pointed out the dire lack of engagement over the past year and the impact this has had on transparency.

Next Steps

While there has been movement in the final few weeks of this year, which is certainly positive, there are still a lot of unknowns and a prevailing sense of uncertainty. At the time of writing, the wording of the compromise text has not yet been officially disclosed: it is paramount that it is disclosed to allow for appropriate public scrutiny. Without engaging with the nuances of the text it is difficult to predict how it will be received by the Commission and the Parliament. Already, civil society organisations are choosing to gloss over minor issues in order to support the compromise and avoid giving the European Commission the space to claim that a solution will never be found, and push the dossier back down the political agenda. We believe it is imperative that the file quickly returns to the formal negotiations in the Trilogue phase to allow the institutions to hammer out a final regulation: to give up now would be a huge disappointment, and a blow to the future of health in Europe.

The next meetings of the EUnetHTA Forum and the EUnetHTA Network Stakeholder Pool are set for April 2021: we will continue to hold EUnetHTA to account in terms of stakeholder engagement and transparency. The EUnetHTA mandate comes to an end in May 2021 so we also must await further information on what might replace it and how that body or process will engage with civil society. Finally, we wish the Portuguese Presidency good luck for its tenure, and hope that it delivers on its commitment to make the most of the renewed momentum driven by its German predecessors. The value of European collaboration and joint health technology assessment has been made even clearer by the COVID-19 crisis, so it is imperative the dossier does not experience any further delays, and that transparency, quality and flexibility remain integral to any solution.

16 December 2020

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