Health Technology Assessment During the COVID-19 Pandemic

An Update and Recommendations for Moving Forward

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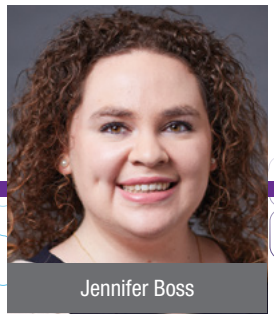
The global COVID-19 pandemic has infiltrated every aspect of daily life with long-lasting effects expected across all sectors, including health technology assessment (HTA) and the market access of pharmaceuticals. Healthcare treatment developers must brace themselves for considerable delays to clinical trials, re-prioritization of pipeline products, and a shift change in normal working practices. As a follow-up to our investigation on the impact of COVID-19 on integrated scientific advice procedures (See "Integrated Scientific Advice during the COVID-19 Pandemic: A Status Update on Key Programs in North American and Europe" in the Spring 2020 issue of *The Evidence Forum*), we now focus on another key area of risk to the commercialization of a new HTA and price negotiations.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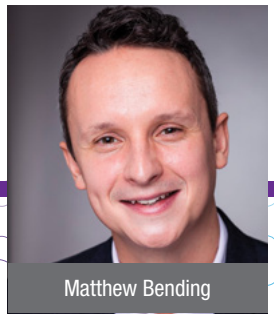
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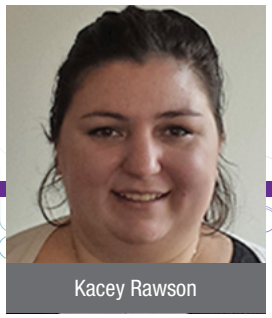
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HTA Overview

Health technology assessment is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle.[1] The purpose is to inform decision making in order to promote an equitable, efficient, and high-quality health system.[1] Distinct from integrated scientific advice which takes place at an earlier stage in the product lifecycle during evidence generation planning (See "An Initial Framework to Describe and Classify Integrated Scientific Advice Procedures: Trends and Developments" in the Fall 2020 issue of *The Evidence Forum*), HTA is an evaluative approach that assesses the impact on society of health technologies and informs decision making regarding the reimbursement of drugs and other health technologies.[2] Since its creation in the 1990's, HTA has become widely implemented across health systems globally and is now a key stage for successful market access.[2] As one indicator of its use, the term "health technology assessment" was entered into Google Ngram Viewer, which displays a graph showing how that phrase has occurred in a corpus of books (e.g., British English, English Fiction, French) over a selected period of years. The frequency with which the phrase is used in books highlights how quickly the terminology has become adopted (See Figure 1). Indeed, justification of reimbursement is now commonly referred to as the fourth hurdle to obtaining a product license after demonstration of product quality, efficacy, and safety.

Throughout 2020, the COVID-19 pandemic has resulted in changes to the status of HTA as institutions reallocate resources to respond to outbreak-related requests and healthcare practitioners provide care to those affected by the pandemic. While there are resulting delays and disruptions to various HTA programs across countries, there are still options available for sponsors seeking assessment and appraisal.

Status of HTA During the Pandemic

A summary of the status of key HTA programs in North America, Europe, and the Asia-Pacific region is presented in Table 1. COVID-19 has had a varying impact on market access across the HTA programs in terms of changes to the format and timeframes of assessment meetings (whereby interactions between the HTA body, sponsor, and Evidence Review Group are held), and prioritization of technologies by the institutions.

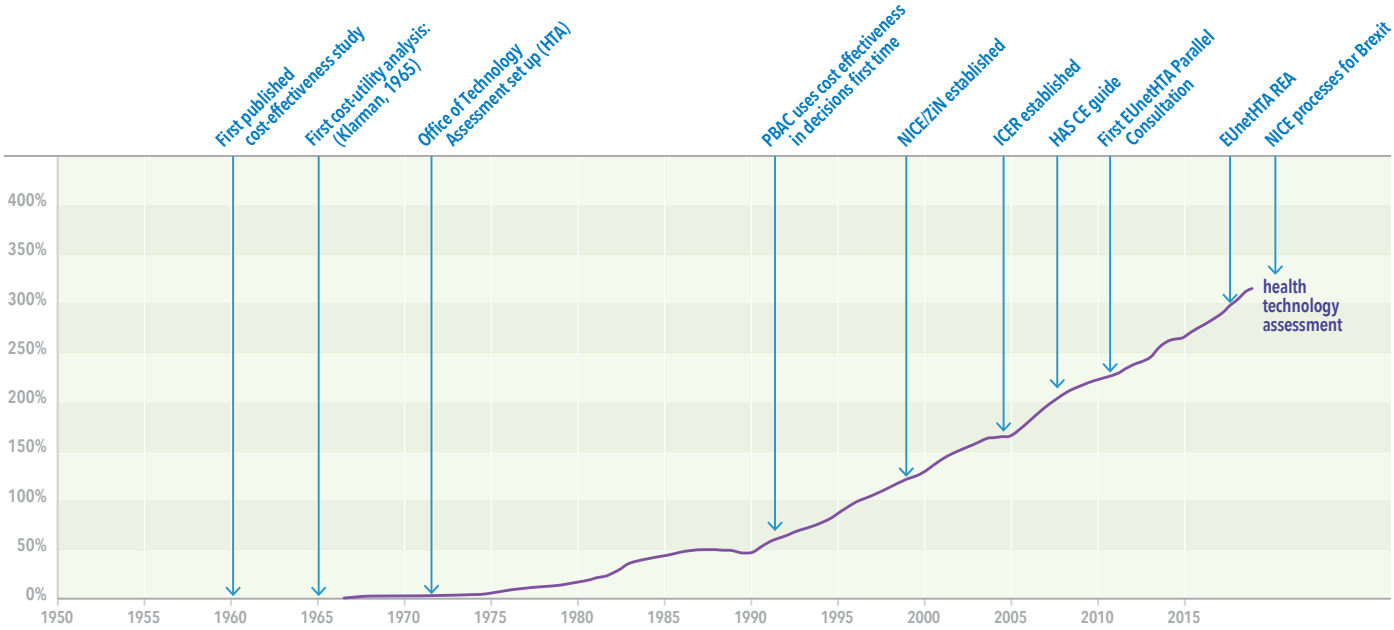
Format

The most widespread change is the switch of meeting format from in-person to virtual which has been implemented across each program by all institutions.

Timeframe

In terms of timeframes, some institutions are conducting their HTA programs as normal with minimal or no impact on assessment timeframes, including the Pharmaceutical Benefits Advisory Committee (PBAC; Australia), Canadian Agency for Drugs and Technologies in Health (CADTH; Canada), Federal Joint Committee (G-BA; Germany), Italian Medicines Agency (AIFA; Italy), National Centre for Pharmacoeconomics (NCPE; Ireland), and Dental and Pharmaceutical Benefits Agency (TLV; Sweden). Other institutions have temporarily suspended their HTA programs during the pandemic, including the Spanish Interministerial Medicinal Products Pricing Committee (CIPM; Spain).

Figure 1. Citation of the Term "Health Technology Assessment" in Books Between 1950 and Today



CE = Cost-effectiveness; PBAC = Pharmaceutical Benefits Advisory Committee; NICE = National Institute for Health and Care Excellence; ZIN = National Health Care Institute; ICER = Institute for Clinical and Economic Review; HAS = Haute Autorité de santé (French National Authority for Health); EUnetHTA = European Network for Health Technology Assessment; REA = Relative Effectiveness Assessment

Although the HAS in France did not suspend meetings, priority therapeutic areas for assessment have been identified (COVID-19, oncology, pediatrics, or any medication in a serious disease with high unmet need) and products which do not fall into these categories are expected to be delayed.

In the United Kingdom, the All Wales Medicines Strategy Group (AWMSG; Wales), National Institute for Health and Care Excellence (NICE; England), and Scottish Medicines Consortium (SMC; Scotland) had temporarily suspended all appraisal meetings for varying lengths of time during the first and second quarters of 2020; however, all three institutions have now resumed their HTA programs which are running with delays (note that the SMC is not currently accepting new submissions or resubmissions). Similarly, the Institute for Clinical and Economic Review (ICER) in the United States (US) also temporarily suspended assessment meetings, but activities have now resumed with a 90-day delay in assessments as of April 2020.

Prioritization of Specific Therapy Areas

Multiple institutions have announced prioritization of certain therapeutic areas for assessment, including products for COVID-19 (including HAS, AIFA, NICE, EUnetHTA, and ICER) or therapeutically critical products for oncology, pediatrics, or diseases with a high unmet need (HAS and NICE).

Short-term Implications

The most immediate challenge facing HTA agencies as they resume normal operations is to clear the backlog of appraisals. For HTA programs such as those at NICE and SMC which have resumed meetings following temporary suspension, delays of at least six months are expected through 2021 (especially for products in non-prioritized therapeutic areas). Although some HTA agencies are trying to help with backlog through the prioritization of disease areas with high unmet need, the criteria for prioritization is not always transparent and this approach is not consistent between the agencies assessed. As a result, considerable variations in delay timeframes across different indications and markets is to be expected.

Recommendation: The exact impact of the predicted delays on the launch timelines of specific products remains to be seen; however, pharmaceutical companies should be reassessing country launch waves, cross-country launch sequencing, and competitor launch forecasting for all late stage products in order to identify new opportunities and prepare for emerging challenges.

Mid-term Implications

All countries assessed have now adopted virtual meetings with face-to-face interactions postponed for the foreseeable future. Therefore, market access teams must adjust their preparations from a face-to-face to a virtual platform. In a virtual setting, it becomes more difficult to communicate within your own team, react to non-verbal cues, and to generate a level of familiarity among attendees. In addition, those attending the meeting will be more reliant on pre-submitted written materials.

Recommendation: Clear and concise value communication across all written deliverables should be prioritized alongside virtual negotiation preparedness training with affiliate teams. Some best practices include:

- Restart computer at least 30 minutes before the meeting with HTA and keep all unnecessary applications closed (including email, as it can be distracting)
- Test video and audio the day before (e.g., Zoom, the platform used by NICE, allows the ability to do a test meeting to check audio and video)
- Keep a separate chat open outside of the HTA meeting for within-team communication
- Ensure microphone is muted when not speaking
- Be aware of one's location and surroundings, ensuring no distractions, room lighting is adequate, etc.
- Dress as you would for a face-to-face meeting

The development of virtual negotiation playbooks, negotiation guidelines, and mock negotiations will enable affiliate teams to suitably prepare for this new setting.

Long-term Implications

The COVID-19 pandemic has put healthcare systems around the world under considerable pressure, and a long-term shift in priorities is predicted across all countries. In addition, the considerable financial cost of dealing with the pandemic will mean healthcare budgets will be even more constrained. This is anticipated to create knock-on effects for pharmaceutical companies; greater difficulty in proving the value of new medications for market access approval, tougher pricing negotiations, and stricter volume restrictions are expected. A lower willingness to pay due to COVID-19 will likely lead to greater evidence requirements in submission dossiers during a time when conducting additional clinical trials is difficult. It is also possible changes to formal or informal thresholds of budget impact and/or cost-effectiveness or international reference pricing approaches may also be forthcoming. NICE, for example, has already announced changes to the HTA appraisal process based on learnings from changes to working practices during the pandemic.[3]

Recommendation: An end date to the prioritization of certain disease areas was not provided by any of the HTA agencies assessed for this article. Therefore, one can only speculate on what this means for the future of prioritization, but it is possible that agencies will move to a new model where products meeting a defined set of criteria no longer need formal appraisal as a way to free up resources

long term. Early and continued engagement with HTA bodies will provide useful insights into this evolving payer landscape. While early stage interactions with HTA and regulatory bodies in the form of integrated scientific advice is emerging to be very beneficial, it may be invaluable during this period of growing uncertainty. As we published previously, many agencies are still offering scientific advice services (albeit remotely) helping companies to understand stakeholder needs and refine their evidence package. In addition, it will be important for pharmaceutical companies to be open to alternative and innovative access arrangements, and aligned customer engagement across the local health ecosystem will be essential to successfully negotiate all stakeholders and decision makers. This will require complex analysis, planning, and engagement at a local level, valuing the contribution of each role. ■

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Table 1: Status of HTA Programs During the COVID-19 Pandemic

Country/ Region	Institution	COVID-19 Impact on:			Changes in Access Priorities	Long-term Implications
			Meeting Timetables	Meeting Location		
Australia	PBAC[4]		**No change** to timing	All meetings being run **virtually**	N/A	N/A
Canada	CADTH[5,6]		**No change** to timing	All meetings being run **virtually**	N/A	N/A
Europe	EUnetHTA[7-9]		**Significant delays** as assessments related to COVID-19 are prioritized	All meetings being run **virtually**	Priority therapeutic area throughout remainder of duration of Joint Action 3 (end of May 2021): COVID-19	Unclear when non-COVID-19 related assessments will resume normally
France	HAS[10]		N/A	All meetings being run **virtually**	Priority therapeutic areas for assessment: COVID-19, oncology, pediatrics, or any medication in a serious disease area with high unmet need	N/A
Germany	G-BA[11]		**No change** to timing; New amendment to allow a **written voting procedure**	All meetings being run **virtually**	N/A	N/A
Ireland	NCPE[12]		**No change** to timing	N/A	COVID-19 Evidence Review Group for Medicines established	N/A
Italy	AIFA[13,14]		**No change** to timing	All meetings being run **virtually**	COVID-19 products	National: N/A Regional: Market access delays are expected at regional level due to staff shortages and re-prioritization of resources
Spain	CIPM[15]		All meetings **suspended** from 4 March 2020	All meetings being run **virtually**	N/A	National: N/A Regional: Market access delays are expected at regional level due to staff shortages and re-prioritization of resources

KEY: = no impact = some impact = significant impact

Country/ Region	Institution	COVID-19 Impact on:			Changes in Access Priorities	Long-term Implications
			Meeting Timetables	Meeting Location		
Sweden	TLV[16]		**No change** to timing	All meetings are being run **virtually**; TLV is not currently receiving any external visits	N/A	While operations are continuing as usual with virtual meetings, a continuity plan has been developed to prioritize activities if necessary
UK	AWMSG[17]		All meetings **suspended** from March to May 2020; Meetings **resumed** from 16 June 2020	All meetings being run **virtually**	N/A	N/A
UK	NICE[18]		All meetings **suspended** for April and May 2020; Meetings **resumed** from 1 June 2020	All meetings being run **virtually**	Priority therapeutic areas for assessment: therapeutically critical (e.g., oncology) and COVID-19	Beginning May 2020, the technical report is replaced by a modified version of the Evidence Review Group (ERG) report so that it is presented in an issues-based style; further changes to the NICE appraisal process are expected in June 2021
UK	SMC[19]		All meetings **suspended** from 22 May 2020; Meetings **resumed** from August 2020 in phased approach	All meetings being run **virtually**	**First phase** of resuming meetings will focus on existing applications that were being processed during the suspension. Some applications may be fast tracked to advice following a review by the SMC Executive. **Second phase** will see the SMC Executive agree on which submissions to review, given the unmet need and availability of other medicines. This is only a temporary step, with the SMC hoping to resume full review of all submissions once the backlog has been cleared.	No new submissions or resubmissions being accepted at the current time
US	ICER[20, 21]		All meetings **suspended** for 90 days beginning in April 2020; All meetings were planned to resume following this pause	N/A	ICER announced adaptations to their value assessment framework for COVID-19-related products to ensure more timely responses	

KEY: = no impact = some impact = significant impact

AIFA = Italian Medicines Agency; AWMSG = All Wales Medicines Strategy Group; CADTH = Canadian Agency for Drugs and Technologies in Health; CIPM = Spanish Interministerial Medicinal Products Pricing Committee; CT = Transparency Commission; ERG = evidence review groups; EUnetHTA = European Network for Health Technology Assessment; G-BA = Federal Joint Committee; HAS = la Haute Autorité de santé; HTA = health technology assessment; ICER = Institute for Clinical and Economic Review; N/A = not available; NCPE = National Centre for Pharmacoeconomics; NICE = National Institute for Health and Care Excellence; PBAC = Pharmaceutical Benefits Advisory Committee; SMC = Scottish Medicines Consortium; TLV = Dental and Pharmaceutical Benefits Agency.

REFERENCES

1. O'Rourke B, Oortwijn W, Schuller T, International Joint Task Group. The New Definition of Health Technology Assessment: A Milestone in International Collaboration. *Int J Technol Assess Health Care*. 2020 Jun;36(3):198-190. doi: 10.1017/S0266462320000215. Epub 2020 May 13.
2. Drummond M, Sorenson C. Nasty or Nice? A Perspective on the Use of Health Technology Assessment in the United Kingdom. *Value Health*. 2009 Jun;12 Suppl;12 Suppl 2: S8-13. doi: 10.1111/j.1524-4733.2009.00552.x.
3. National Institute for Health and Care Excellence (NICE). Coronavirus (COVID-19). Available at: https://www.nice.org.uk/covid-19. Accessed September 7, 2020.
4. Australian Government Department of Health. The Pharmaceutical Benefits Scheme. Available at: https://www.pbs.gov.au/info/news. Accessed September 7, 2020.
5. CADTH. COVID-19 Update. Available at: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/covid-19-update. Accessed September 7, 2020.
6. CADTH. CADTH Pharmaceutical Reviews Update – Issue 15. Available at: https://www.cadth.ca/cadth-pharmaceutical-reviews-update-issue-15. Accessed September 7, 2020.
7. European Network for Health Technology Assessment (EUnetHTA). COVID-19 Response. Available at: https://eunethta.eu/services/covid-19/. Accessed on September 7, 2020.
8. European Network for Health Technology Assessment (EUnetHTA). Statement from the EUnetHTA Secretariat on COVID-19. Available at: https://eunethta.eu/statement-from-the-eunethta-secretariat-on-covid-19/. Accessed September 7, 2020.
9. EUnetHTA. EUnetHTA Response to COVID-19. Available at: https://eunethta.eu/eunethta-response-to-covid-19/. Accessed September 7, 2020.
10. Haute Autorité de Santé. Commissions Prioritize Health Products to be Evaluated. Available at: https://www.has-sante.fr/jcms/p_3167555/fr/les-commissions-priorisent-les-produits-desante-a-evaluer. Accessed September 7, 2020.
11. Gemeinsamer Bundesausschuss (G-BA). Public Meetings of the G-BA. Available at: https://www.g-ba.de/service/oeffentliche-sitzungen/. Accessed September 7, 2020.
12. National Centre for Pharmacoeconomics (NCPE Ireland). COVID-19. Available at: http://www.ncpe.ie/news/covid-19/. Accessed September 7, 2020.
13. AIFA Italian Pharmaceutical Agency. Ristabilite le ordinarie modalità operative dei Registri di monitoraggio AIFA dopo la fase di sospensione per emergenza epidemiologica da COVID-19. Available at: https://www.aifa.gov.it/web/guest/-/ristabilite-le-ordinarie-modalita-operative-dei-registri-di-monitoraggio-aifa-dopo-la-fase-di-sospensione-per-emergenza-epidemiologica-da-covid-19. Accessed September 16, 2020.
14. AIFA Italian Pharmaceutical Agency. Extending the Compilation of AIFA Monitoring Logs. Transitional Measures for Containment and Management of the Epidemiological Emergency from COVID-19. Available at: https://www.aifa.gov.it/-/proroga-della-compilazione-dei-registri-di-monitoraggio-aifa. Accessed September 7, 2020.
15. Gobierno de Espana. Comision Interministerial de Precios de Medicamentos y Productos Sanitarios. Available at: https://www.mscbs.gob.es/profesionales/farmacia/CIPMyPS.htm?utm_source=diariofarma&utm_mediumnk. Accessed September 17, 2020.
16. The Dental and Pharmaceutical Benefits Agency (TLV). COVID19 and Processing Times. Available at: https://www.tlv.se/om-oss/press/nyheter/arkiv/2020-03-23-covid19-och-handlaggningstider.html. Accessed September 7, 2020.
17. All Wales Medicines Strategy Group. COVID-19 Update. Medicines Advice and Medicines Optimization Resources. Available at: http://www.awmsg.org/meetings_awmsg_2020.html. Accessed September 7, 2020.
18. National Institute for Health and Care Excellence (NICE). Coronavirus (COVID-19). Available at: https://www.nice.org.uk/covid-19. Accessed September 7, 2020.
19. Scottish Medicines Consortium. SMC Response to COVID-19. Available at: https://www.scottishmedicines.org.uk/about-us/latest-updates/smc-response-to-covid-19. Accessed September 17, 2020.
20. Institute for Clinical and Economic Review (ICER). ICER Indefinitely Postpones Public Meetings for Sickle Cell Disease and Cystic Fibrosis: Expands Other Assessment Timelines Up to Three Months. Available at: https://icer-review.org/announcements/covid19_hiatus/. Accessed September 7, 2020.
21. ICER. Adaptions to the ICER Methods for Evaluation of Therapies for COVID-19. 2020 July 18. Available at: https://icer-review.org/wp-content/uploads/2020/07/Adaptations-to-the-ICER-methods-for-evaluation-related-to-treatments-for-COVID_July18.pdf. Accessed September 17, 2020.