The impact of Covid-19 on European HTA decisions

Watson C, Petrie JL, Toomey JA, Shaw CA
PHMR, Berkeley Works, London, UK

Objectives

The global COVID-19 pandemic has presented huge healthcare challenges, leading to regulatory changes, the suspension of many clinical trials not directly influenced by COVID-19 and alterations in drug technology assessment (TA) practices [1, 2]. The aim of this review was to investigate the impact of the COVID-19 pandemic on the processes of European health technology assessment (HTA) agencies, including the initial changes to routine practice and the impact of these changes on the number and type of assessments published.

Methods

- TAs published by the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), Haute Autorité de Santé (HAS) and Gemeinsamer Bundesausschuss (G-BA) during the last 2 years were identified and compared
- Adaptations to current assessment practices were established for each HTA agency, including timelines where available
- Descriptive analysis was used to summarise appraisal trends prior to COVID-19, following initial adaptive procedures, and longer-term follow-up

Results

Adaptions to current assessment practices *(Figure 1)*

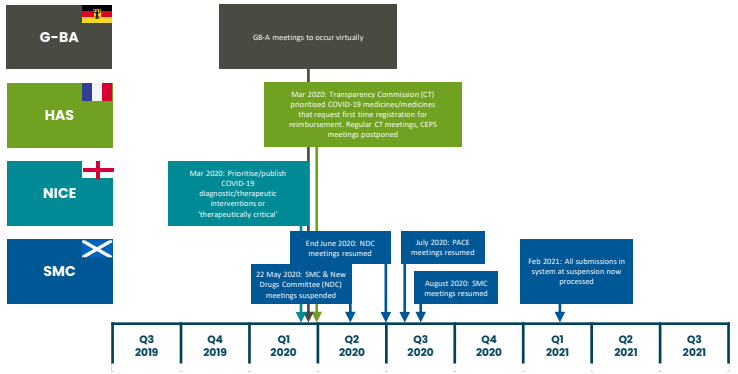
- SMC assessments were absent between May and July 2020, with a subsequent phased approach including scope for 'fast-track to advice' after SMC executive review; medicines with the potential to deliver the greatest benefit to patients were prioritised for assessment, i.e., 'first in class' therapeutic areas or where there were no other treatments [3]
- In March 2020, NICE prioritised work related to addressing COVID-19 diagnostic or therapeutic interventions and medicines deemed 'therapeutically critical' [4], subsequently defined as:

  "Essentially all technology appraisals involving a cancer medicine are considered therapeutically critical, except for cancer drugs fund reviews. A small number of non-cancer medicines have also been designated as therapeutically critical" [4]
- In France, the Transparency Commission prioritised drugs intended to manage COVID-19 and new TAs or extension of indication assessments in oncology, paediatrics, and in serious illnesses with an unmet medical need [5]. Meetings occurred regularly, although weekly CEPS meetings were postponed [6]
- In Germany, G-BA meetings were held virtually to minimise delays to process requests for consultation [7]

Trends in TA publications *(Table 1)*

- There was a substantial drop in the total number of SMC assessments during the initial COVID response but an increase in the subsequent 6-month period. The 6-month period from March – August 2021 saw a return to pre-COVID levels. The number of assessments pertaining to cancer did not increase during the COVID period

Figure 1. *Timeline comparing the impact of COVID-19 on the procedures at each HTA agency. Image not to scale.*



- NICE published only one assessment per month in March and April 2020; there was a subsequent increase in total assessment numbers from September 2020 to August 2021 compared to pre-COVID levels (Table 1). A higher percentage of assessments pertaining to cancer were also noted during the 18-month COVID period
- There were no notable trends between the total number of appraisals published by HAS in the pre-COVID period and the 18-month COVID period (Table 1). Furthermore, there was no pattern in the percentage of appraisals pertaining to cancer. The number of appraisals published in February and August 2020, and in February and July 2021, was reduced
- In Germany, no trends were apparent between the total number of appraisals published in the pre-COVID period and during the 18-month COVID period (Table 1). There was no pattern in the percentage of appraisals pertaining to cancer

Table 1. *Six-month trends in HTA appraisals pre-COVID and following COVID lockdown.*

		Pre-COVID (Sept 2019 – Feb 2020)	COVID (Mar 2020 – Aug 2020)	COVID (Sept 2020 – Feb 2021)	COVID (Mar 2021 – Aug 2021)
SMC	TAs published	49	16	61	46
	Cancer	26 (53%)	4 (25%)	29 (48%)	18 (39%)
NICE	TAs published	26	20	37	44
	Cancer	11 (42%)	14 (70%)	21 (57%)	26 (59%)
HAS	TAs published	163	163	139	146
	Cancer	45 (28%)	52 (32%)	26 (19%)	29 (20%)
G-BA	TAs published	60	68	51	88
	Cancer	23 (38%)	35 (52%)	15 (29%)	38 (43%)

Discussion

- Our review of European HTA decisions determined that there were inevitable differences between HTA agencies in their response to COVID-19
- SMC appraisals were substantially impacted during the initial COVID period due to suspension of SMC and New Drugs Committee (NDC) meetings, with no assessments published from May - July 2020. The subsequent increase, possibly due to the "fast tracking" of advice announced in July, [3] resulted in all medicines that were in the system at the time meetings were suspended being processed by February 2021. Appraisal numbers have now returned to pre-COVID levels
- The number of NICE appraisals was minimally impacted during the 18 month COVID period. The higher percentage of cancer assessments likely reflects the decision to prioritise appraisals involving a cancer medicine
- HAS appraisals were not significantly affected by the COVID-19 pandemic. There was no announcement to indicate why appraisal publications were reduced during the months of February and August 2020, and February and July 2021; reductions could be attributable to spikes in COVID-19 infection rates. There were no notable changes in the number of published cancer appraisals over time
- COVID-19 had no substantial impact on G-BA appraisal publications. This was expected following the announcement that appraisal meetings would occur virtually

Conclusions

Despite the individualised approach in response to the challenges of COVID-19, European HTA agencies demonstrated minimal long-term impact and a return to normal drug TA output. However, as highlighted by Lorgelly and Adler (2020), longer-term impact of COVID-19 may not be observed until years later due to delays in 'discoveries and initial experiments' and the potential for 'underpowered studies' as a result of trial suspension [1].

References

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Contact: Catherine Watson, Market Access Research Scientist
Tel: +44 (0) 20 3432 7450 E-mail: catherine.watson@phmr.com
PHMR Ltd., Berkley Works, Berkley Grove, London, NW1 8XY