PNS173

What Impact Did COVID-19 Have On HTA Bodies and Pharmaceutical Company Pricing and Market Access Activities?

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Introduction

- Health technology assessment (HTA) bodies and pharmaceutical companies were forced to react to an unprecedented level of disruption due to the early impact of the COVID-19 pandemic.
- This study aims to determine the impact of the early-stage COVID-19 pandemic on the processes of European HTA bodies (Transparency Committee (TC), France; G-BA, Germany; NICE, England; SMC, Scotland; AIFA, Italy; CIPM, Spain) (March-April 2020).
- Additionally, this study also assessed the impact of the pandemic on the activities of pharmaceutical companies within the same time period.

Methods

- NICE, SMC, G-BA, AIFA, TC and CIPM guidelines were analysed to assess how COVID-19 has affected HTA decision-making in Europe.
- We conducted an online survey with 11 pricing and market access (PMA) executives from a range of companies (large pharmaceutical companies to small biotechs), covering the following key topics:
  - Whether COVID-19 had impacted access of marketed products
  - The primary internal company and payer / HTA challenges faced
  - Factors that would impact future PMA activities

Results

- The short-term impact on COVID on the activities of European HTA agencies was mixed. While some EU HTA agencies were able to continue activities virtually, others prioritised critical medicines, or suspended decision making entirely (Table 1).

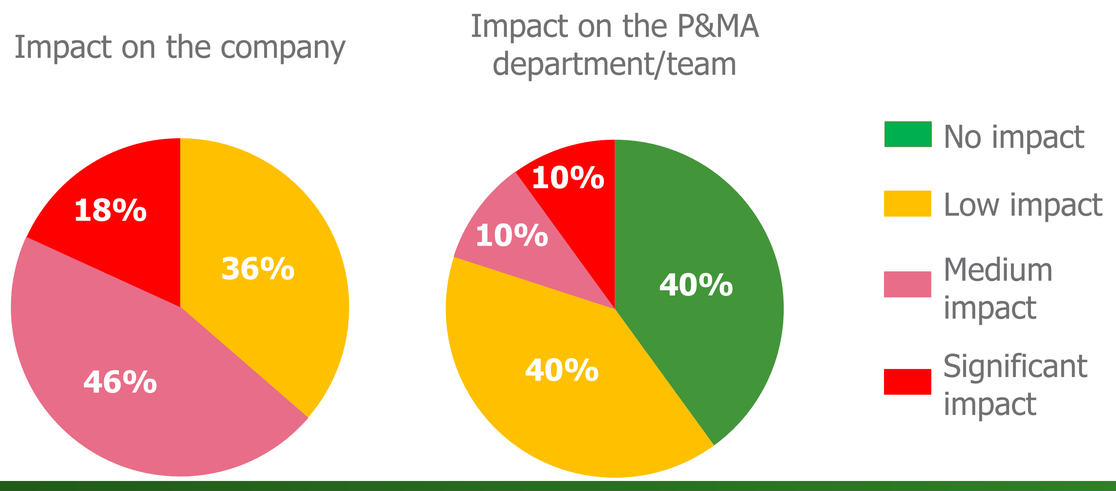
Table 1: Impact of COVID-19 on P&MA decision making

Agency (Country)	Impact on P&MA decision making
SMC (Scotland)	NDC and SMC meetings due to take place in March-May 2020 were cancelled
NICE (England)	Only "therapeutically critical" assessments, oncology and COVID-19 diagnostic/ therapeutic interventions were undertaken in the short term
DGFPS (Spain)	DGFPS, GCPT and CIPM activities continued but outputs expected to be significantly delayed. Regional access discussions were restricted
G-BA (Germany)	No delays in assessments as meetings occurred virtually
HAS (France)	TC meetings occurred on schedule, but weekly CEPS (pricing) committee meetings were postponed
AIFA (Italy)	CTS (clinical) and CPR (pricing) meetings occurred remotely. Internal COVID-19 crisis unit established

No impact on P&MA decision making | Some impact on P&MA decision making | Serious impact on P&MA decision making

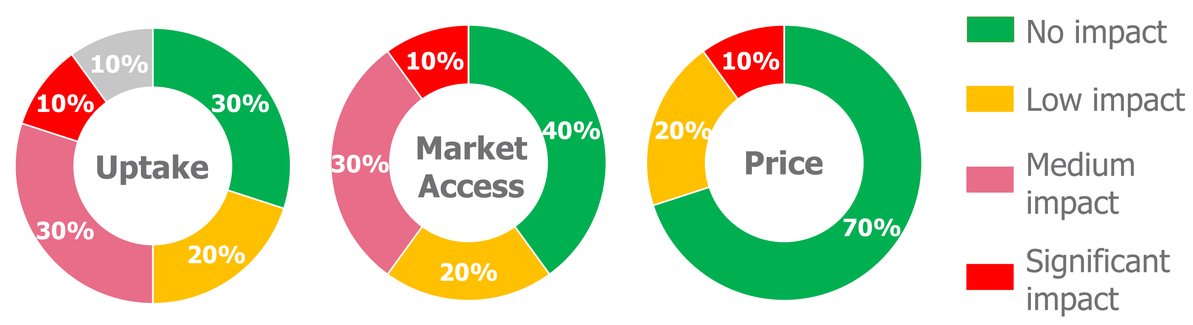
- The survey revealed that the difficulties faced by HTA agencies were also being felt by those working for pharmaceutical companies. All respondents acknowledged that COVID-19 had an impact on their company, with 64% believing this impact to be medium-to-significant (Figure 1).
- However, in contrast, only 20% of P&MA teams thought that there had been a medium-to-significant impact to their operations.

Figure 1: Impact of COVID-19 on the pharmaceutical industry



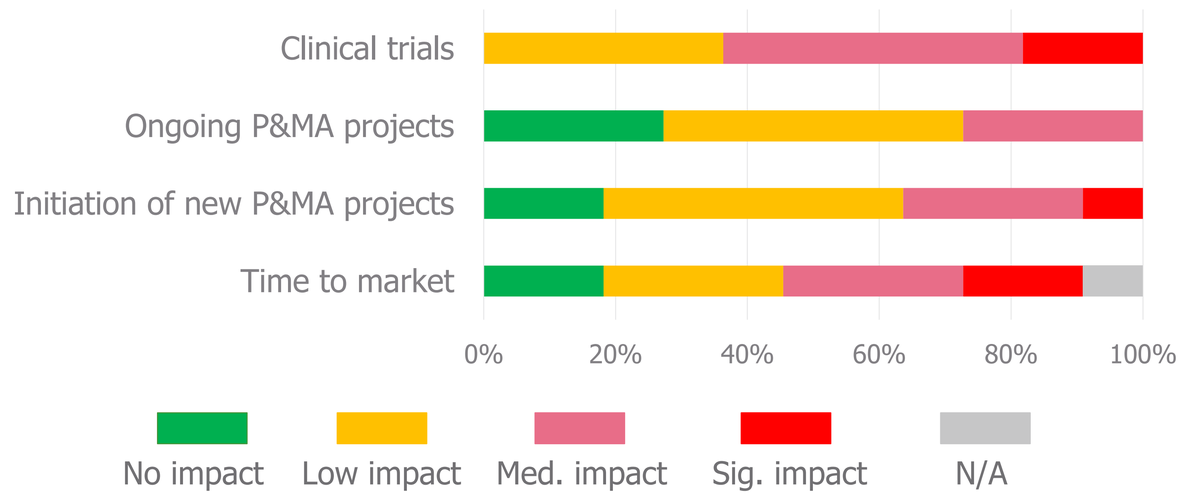
- For launched products, over 60% of companies observed an impact on uptake and/or market access due to COVID-19. 40% of companies believed that the impact on uptake had been medium-to-significant, as had the impact on market access.
- However, respondents observed only limited short-term impact on list or net price, with over 70% of respondents seeing no impact.

Figure 2: Impact of COVID-19 on launched products



- All respondents stated that COVID-19 had impacted clinical trials, with recruitment difficulties, trial pauses and validity concerns cited as reasons for the impact Figure 3)
- Over 80% of respondents had their ability to initiate new P&MA projects disrupted. Ongoing P&MA and field activities, however, were less severely affected, as over 70% respondents believed there to be no or low impact
- These challenges resulted in over 50% respondents expecting up to 6-month delays in the launch of new products, which is also reflected by the delays in HTA decision-making

Figure 3: Impact of COVID-19 on pipeline products



Discussion and conclusions

- Whilst COVID-19 was significantly affecting the decision-making processes of HTA agencies and the pharmaceutical companies as a whole, there was limited impact on the function of P&MA teams.
- For launched products, the respondents found the largest impact was on uptake. This was primarily due to the inability to engage with payers and/or key customers, usually at the regional and local level, resulting in delayed access decisions and the loss of opportunity to promote their therapies.
- For pipeline products, launch of pipeline products was being delayed due to suspended clinical trials, with recruitment difficulties, trial pauses and validity concerns cited as reasons for the slowdown. Disrupted P&MA activities were also an issue as a result of short-term budgetary uncertainty; where activities could be conducted virtually (e.g. ongoing P&MA activities), the impact was less significant.
- While respondents saw the short-term external challenges in the continuity of reimbursement processes by HTA agencies, there was wider concern around the longer-term impact on the healthcare system and the implications future market access and pricing.
- When this survey was completed, the longer-term impact was unknown. Since then, the majority of pharmaceutical companies have bounced back and HTA bodies have adapted their processes to deal with the backlog, but some delays still remain.

AIFA: Italian Medicines Agency; CEPS: Comité Economique des Produits de Santé; CIPM: La Comisión Interministerial de Precios de los Medicamentos; CPR: Comitato Prezzi e Rimborso; CTS: Comitato Tecnico Scientifica; DGFPS; Dirección General de Farmacia y Productos Sanitarios; HTA: Health technology assessment; G-BA: Federal Joint Committee; GCPT: Therapeutic Positioning Report Coordination Group; NDC: New Drugs Committees; NICE: National Institute for Care and Health Excellence; SMC: Scottish Medicines Consortium; TC: Transparency Committee

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