How aware are biotech and pharmaceutical companies of the implementation of the new EU HTA?

HTA33

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INTRODUCTION

After being ratified in early 2022, the Regulation (EU) 2021/2282 joint EU HTA will come into effect in 2025 for selected products, establishing an EU-wide joint assessment of clinical effectiveness (JCA)[1].

This will have wide-reaching changes on how HTA and early scientific advice is conducted in Europe and aims to replace the simultaneous evaluations of clinical data conducted by multiple country-specific HTA bodies.

METHODS

In June 2024 an online survey was re-distributed to industry executives from biotechnology and pharmaceutical companies, with most respondents being from medium to large companies across a range of internal teams including health economics and outcomes research (HEOR), pricing, market access and global market strategy. Data was received from 52 respondents. Responses were compared to our previous survey conducted in 2022.

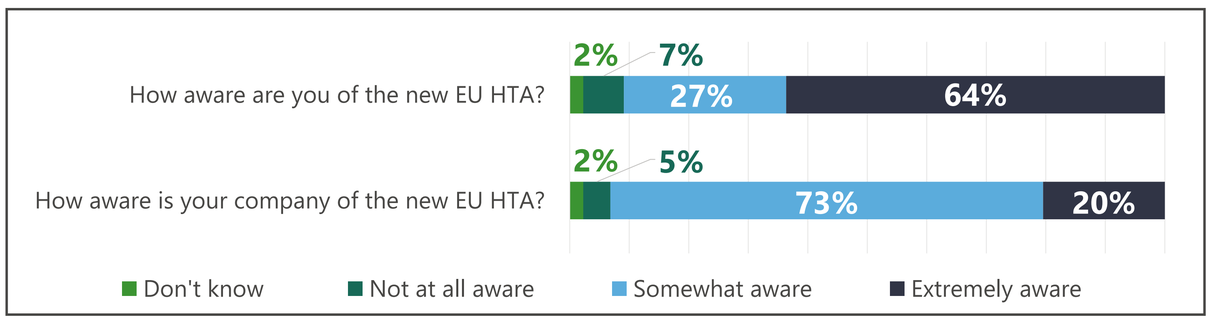
OBJECTIVES

1. Gauge the current awareness of the new EU HTA process within the pharmaceutical industry
2. Understand the levels of preparation within the industry for EU HTA
3. What is the perceived impact of EU HTA on companies and why
4. Identify the challenges and opportunities the pharmaceutical industry envisions with JCA
5. Understand the reasons why companies have taken a particular approach to address JCA considerations

RESULTS

WHAT ARE THE CURRENT LEVELS OF AWARENESS OF EU HTA?

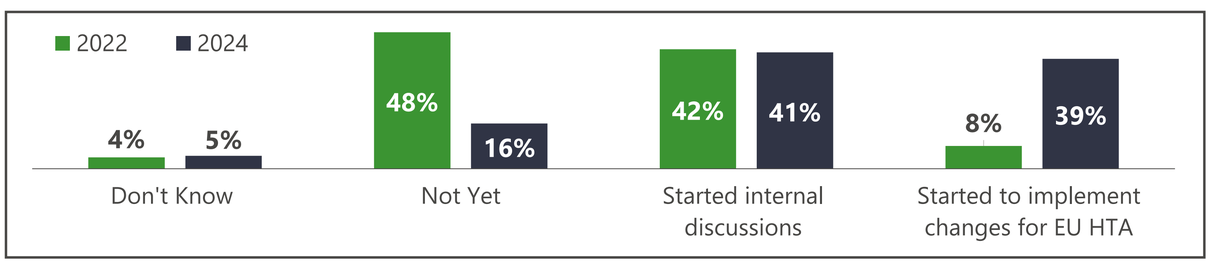
Figure 1: Awareness of the biotechnology and pharmaceutical industry of EU HTA



- 43% of the respondents who answered believed that the process has been clearly communicated, a significant increase over the 22% who believed this in 2022 although this is still below half, especially with the first phase due to come into effect next year

HOW PREPARED ARE COMPANIES FOR THE START OF EU HTA?

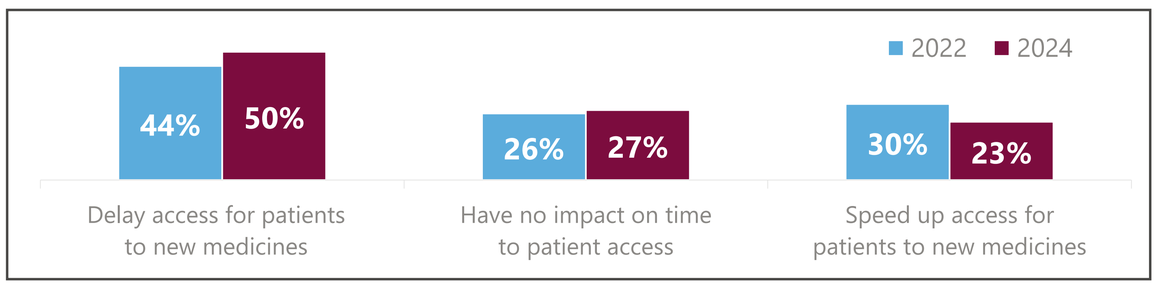
Figure 2: Levels of preparedness for EU HTA among pharmaceutical companies



- The majority of companies have now either begun internal discussions or have actively started to implement changes in preparation for the EU HTA
- Preparations include process changes, the startup of internal working groups, and some have mentioned the hiring of specific roles for EU HTA
- Companies actively preparing for EU HTA include those who do not envision having products involved in EU HTA until 2028, although they do not make up the majority

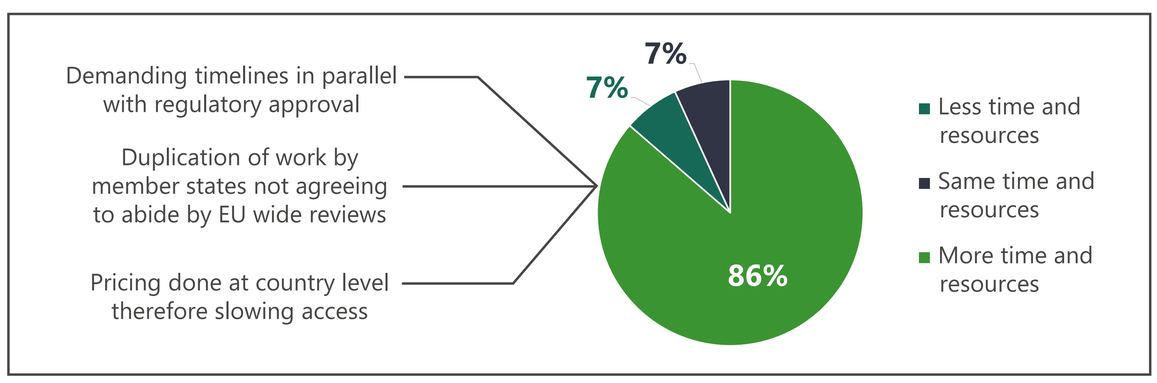
WHAT'S THE IMPACT ON COMPANIES, NEW PRODUCTS, AND GENERAL ATTITUDES TOWARD THE LEGISLATION?

Figure 3: The perception of the impact of EU HTA on the speed of access for patients



- The perception of how EU HTA will impact patient access has not changed significantly since 2022, with the slight trend being towards delaying access
- Some respondents believed that companies would be hesitant of launching ATMPs and new oncological products in Europe in the next 2-3 years until the process is clearer, thereby delaying access for those patients

Figure 4: Perception of how the new EU HTA will impact time and resourcing



- The vast majority of respondents now believe that the upcoming EU HTA will increase time demands for companies, a significant increase from 2022, when only 52% held this view

CONCLUSIONS

1. Overall awareness of EU HTA is high and has increased since 2022. Additionally, there has been a significant increase in the number of companies making active preparations for the beginning of EU HTA. However, almost half of companies still believe that details of the EU HTA processes have not been clearly communicated.
2. Respondents anticipate that EU HTA will delay access for patients, especially for the next 2-3 years, while companies observe how the process works, and we share their opinion
3. Opinions towards the EU HTA process are largely negative, with concerns about an increased resource burden required for successful market access, a sentiment that is the antithesis of the original purpose of the EU HTA. Respondents feel that individual member states will keep extensive country assessments, as an EU-wide process cannot address local concerns, and therefore, the initiative will only add an additional hurdle for companies to navigate
4. Joint EU HTA is fast approaching realisation and with the first products potentially entering the process in a matter of months companies need to be actively making changes to their internal workflows, especially if launching oncology products or ATMPs. However, those with orphan products launching in 2028 also need to be planning for this in the coming years and should be closely monitoring the initial EU HTA assessments

REFERENCES

1. European Parliament, Council on Health Technology Assessment. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. In: European Union, 2021/2282. EUR-Lex: 2021

Abbreviations:

ATMPs: Advanced therapy medicinal products; HEOR: Health economics and outcomes research; HTA: Health technology assessment; JCA: Joint clinical assessment

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