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

PT26

Authors Bean, S[1]; Foxon, G[1]; Hewitt, C[1]

[1]Remap Consulting, Cheshire, United Kingdom

INTRODUCTION

After being ratified in early 2022, the Regulation (EU) 2021/2282 will bring joint EU HTA 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.

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 EUHTA
3. What is the perceived impact of EUHTA on companies and why?

- We also identified what challenges and opportunities the pharmaceutical industry envisions when the new regulations come into force then understand the reasons why companies have taken a particular approach

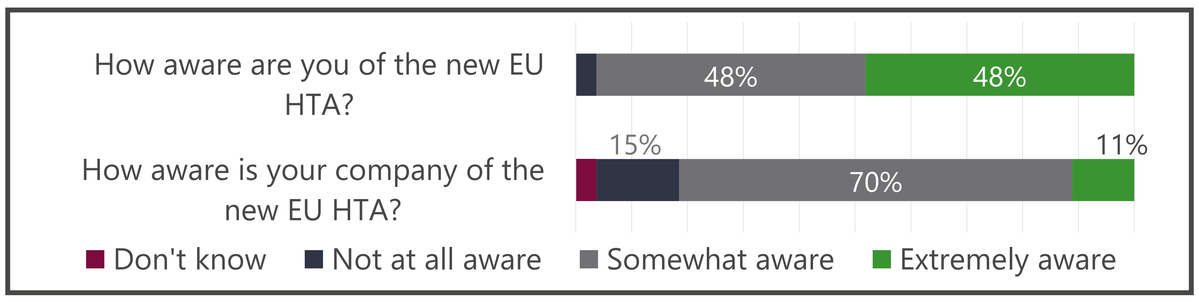
METHODS

An online survey was distributed to 30 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.

RESULTS

WHAT ARE THE CURRENT LEVELS OF AWARENESS OF EUHTA?

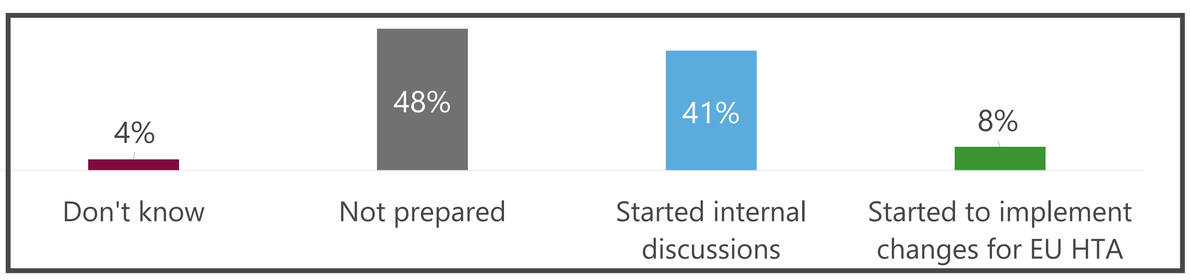
Figure 1: Awareness of the biotechnology and pharmaceutical industry of EU HTA



- Only 22% of the respondents felt that the process has been clearly communicated, with respondents unclear as to what will be required in the EU HTA submission

HOW PREPARED ARE COMPANIES FOR THE START OF EUHTA?

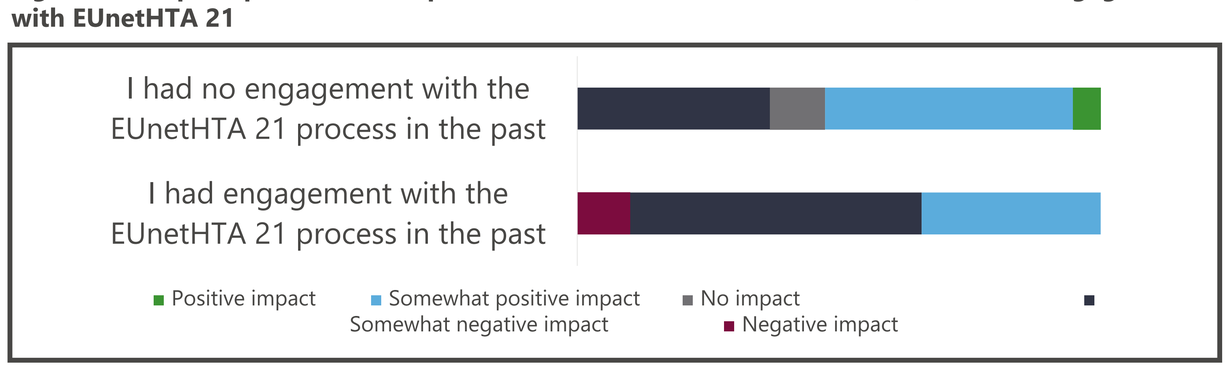
Figure 2: Levels of preparedness for EU HTA among pharmaceutical companies



- Approximately half of companies surveyed have begun some form of internal preparation
- Reasons for not preparing yet include lack of time/resources, insufficient information on EU HTA and those without products launching soon enough warrant discussions

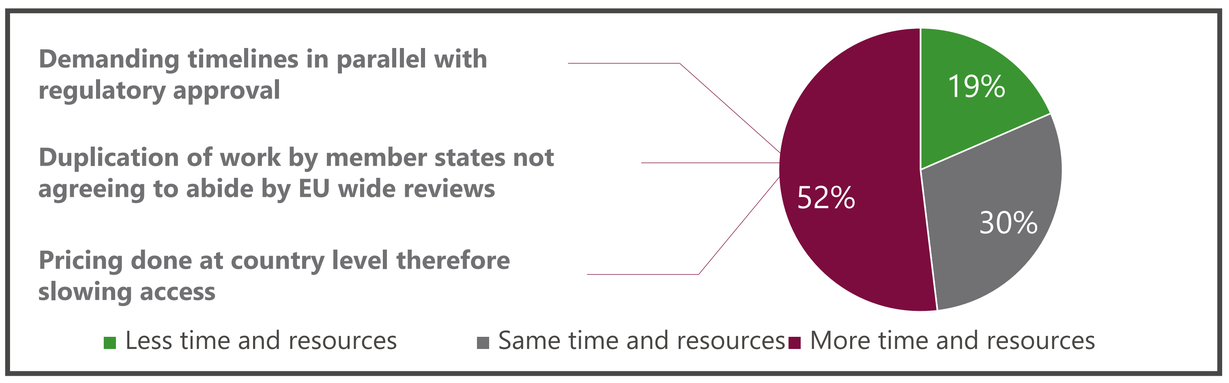
WHAT'S THE IMPACT ON COMPANIES, NEW PRODUCTS, AND GENERAL ATTITUDES TOWARD THE LEGISLATION?

Figure 3: The perception of the impact of EUHTA between those that were/were not engaged with EUnetHTA 21



- 48% of respondents believe the new EU HTA process will have a negative impact on their company, and this rises to 75% in respondents who have experience with EUnetHTA21

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



- Over half of respondents thought EUHTA would increase the burden on companies
- Although, 48% thought it would reduce time to market by requiring only a single dossier

DISCUSSION AND CONCLUSIONS

- Whilst overall awareness of EU HTA is high there is uncertainty as to how pharmaceutical companies will adapt their processes to meet the increased resources required to deliver an EU HTA dossier. This is partly due to the perception among the majority of respondents that the detailed processes of EUHTA have not been clearly communicated
- We anticipate that companies with orphan products in the pipeline are waiting to see how the first phase of JCAs (for oncology products) proceed before beginning to implement internal changes ahead of the second phase of the EUHTA in 2028
- 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 EUHTA. However, respondents acknowledge that the JCA provides an opportunity for better alignment on evidence requirements across countries and could speed up patient access in countries willing to use the JCA to form the basis of price negotiations. The general negative feeling towards the EU HTA shown in this survey also mirrors industry statements
- Joint EU HTA is fast approaching realisation and with less than two years until products start to enter the process in 2025 manufacturers need to start thinking about what impact the new process could have for them and what plans they could action to navigate in these changing waters

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

ISPOR Europe 2023 – Copenhagen, Denmark