Remap

Are pharmaceutical and medical device manufacturers ready for the new EU HTA process?

SURVEY RESULTS

December 2022

Executive summary

In early 2022, the EU HTA regulation was formally ratified with the aim of establishing an EU-wide joint assessment of clinical effectiveness (JCA) starting from 2025 for some products. The JCA is non-binding, with EU Member States free to make their own conclusions on market access and pricing

We surveyed 30 industry executives to gauge how aware and prepared the pharmaceutical industry is for the new EU HTA process and the general attitudes and expectations towards it

While 2025 is rapidly approaching and joint scientific consultations have already been initiated, less than 10% of companies have started implementing changes at an EU or global level to meet the needs of the JCA

Most respondents consider that the EU HTA process has not been communicated clearly so far with significant uncertainties remaining, for example regarding how comparators, endpoints and subgroups will be selected across the member states

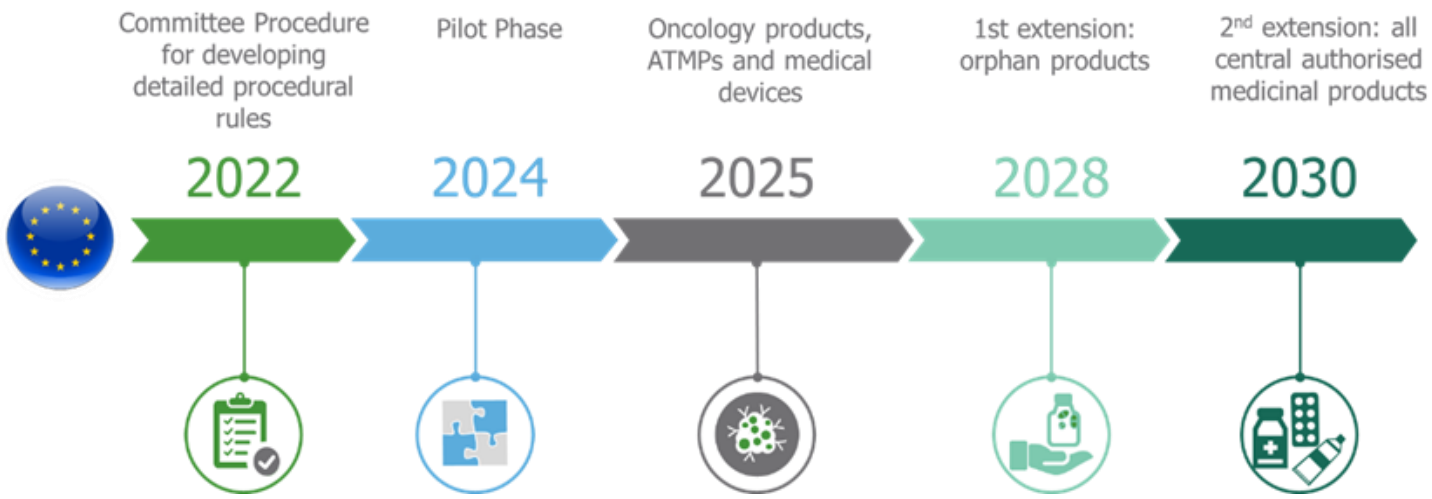
Opinions towards the EU HTA process from respondents are largely negative, with perceptions that it will increase the time and resource burden on companies and not speed up patient access to new drugs. Many expect that country-specific dossiers will still be needed

However, respondents acknowledge that the JCA provides an opportunity to achieve better alignment on evidence requirements across countries, and could potentially speed up patient access in countries willing to use the JCA to form the basis of price negotiations

HTA: Health Technology Assessment; JCA: Joint Clinical Assessment

We conducted a survey to gain an understanding of how prepared the pharmaceutical industry is for the new EU HTA processes

- In early 2022, the EU HTA regulation was formally ratified with the aim of establishing **an EU-wide joint assessment of clinical effectiveness** with an accompanying process for joint early scientific dialogue with EU HTA agencies



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Who completed our survey?

We surveyed 30 respondents from a biotech and pharmaceutical companies.

Our sample comprised of industry executives across a range of top internal teams, including:

- HEOR/Pricing
- Market Access
- Global market strategy

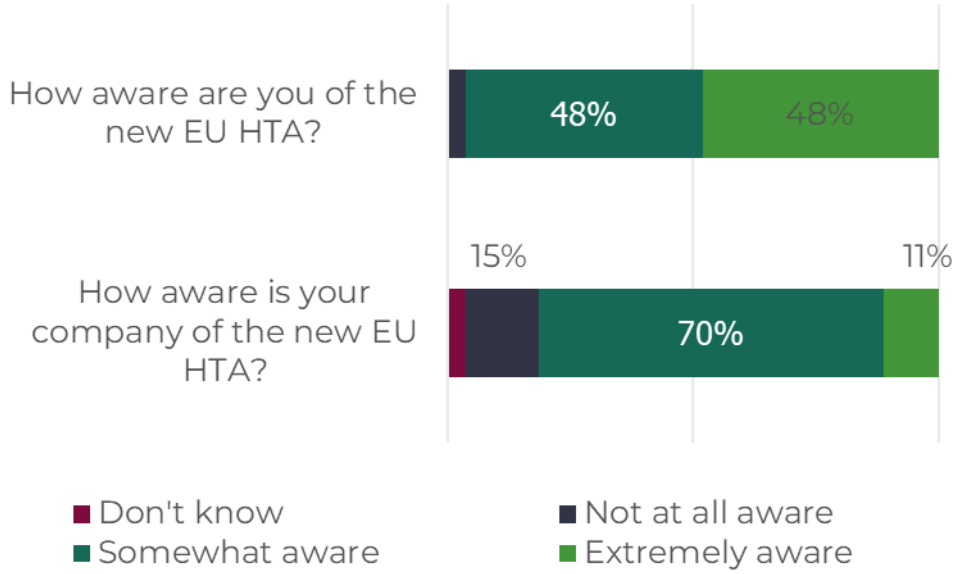
Most of them were representatives from mid to large-sized companies

30% of our respondents had a previous engagement in the EUnetHTA, a workstream that sought to establish an EU-wide joint assessment of clinical effectiveness

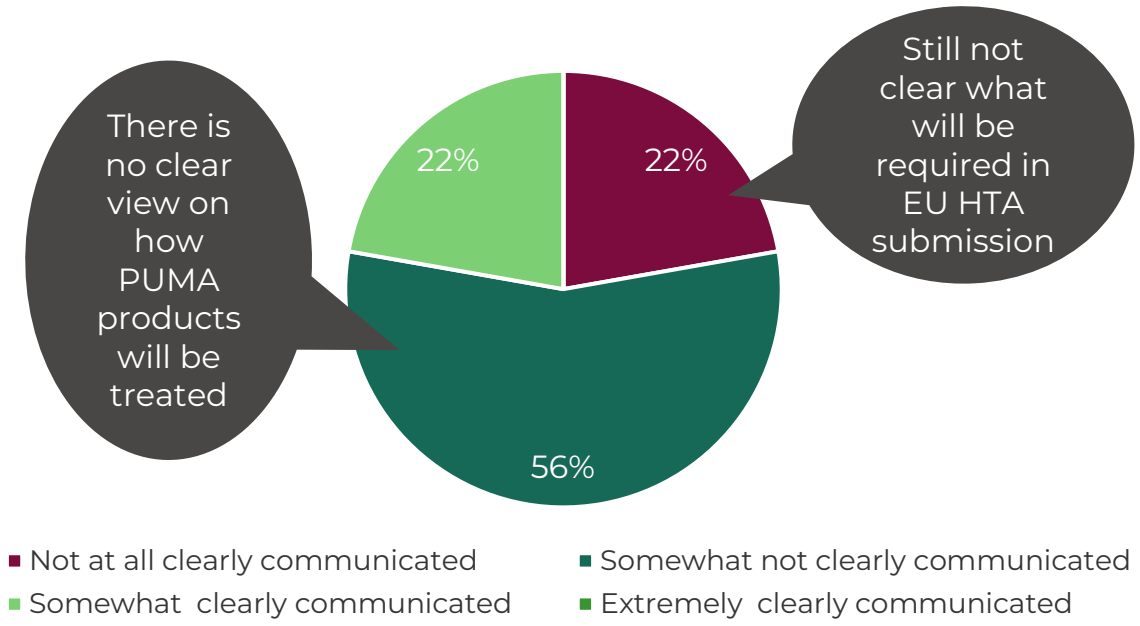
HTA: Health Technology Assessment; HEOR: Health Economics and Outcomes Research

Although the awareness of the new EU HTA process is high, the vast majority of respondents did not feel that it has been communicated clearly

97% of the respondents were to some extent aware of the new EU HTA process



Only 22% of the respondents felt that the process has been clearly communicated; none thought it has been communicated extremely well

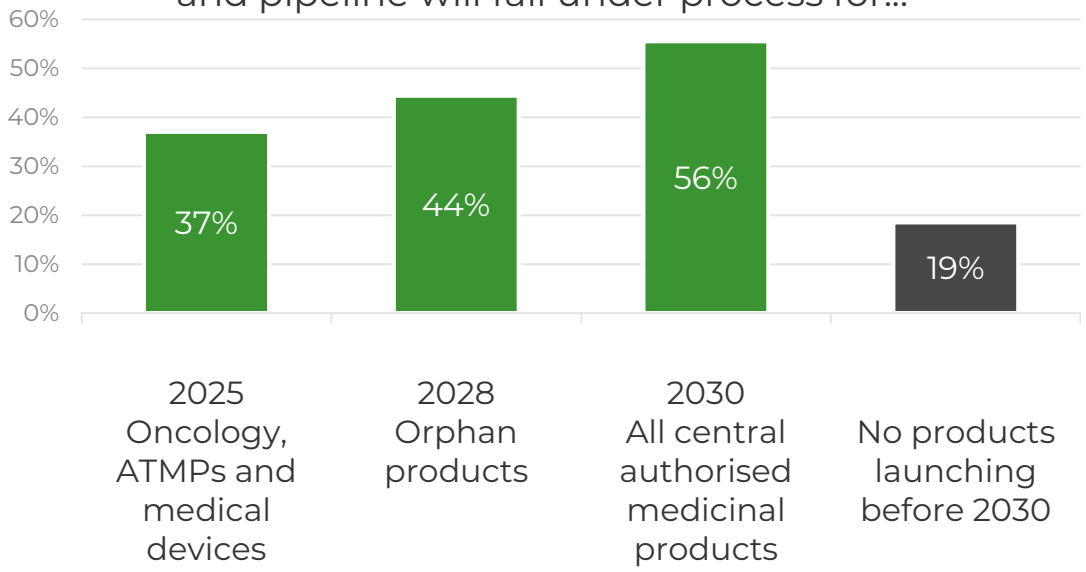


HTA: Health Technology Assessment; PUMA: Paediatric-use marketing authorisation

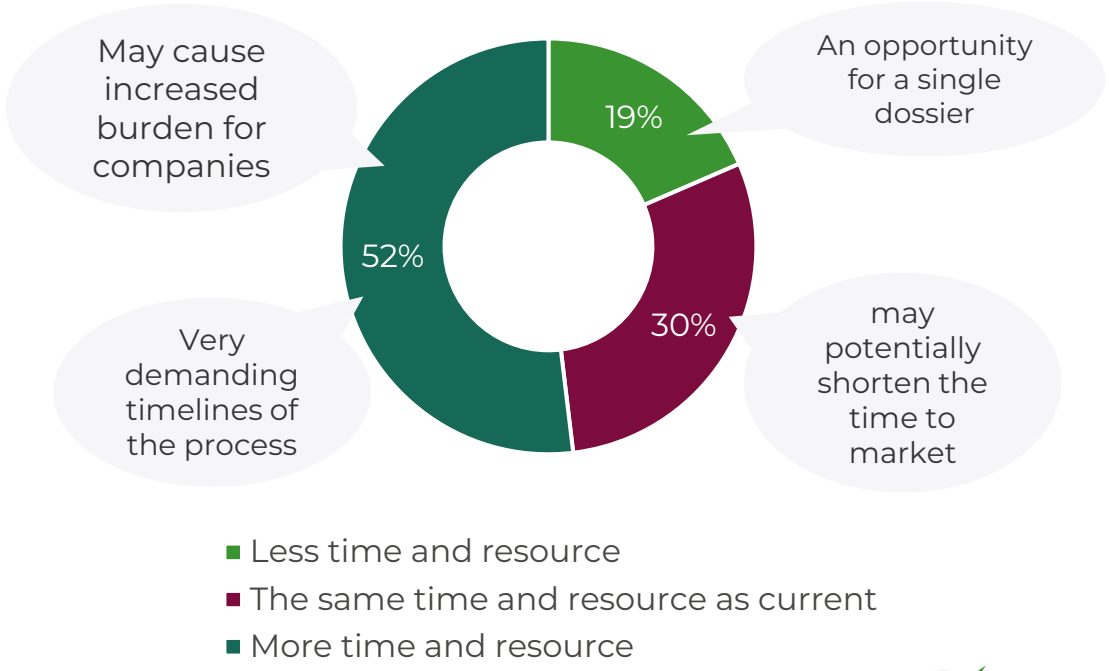
Most companies will be affected by at least one of the scheduled processes, with the majority of companies thinking that they will not save on time and resources

Many predict the new processes to be more time and resource consuming

The products from my company's portfolio and pipeline will fall under process for...

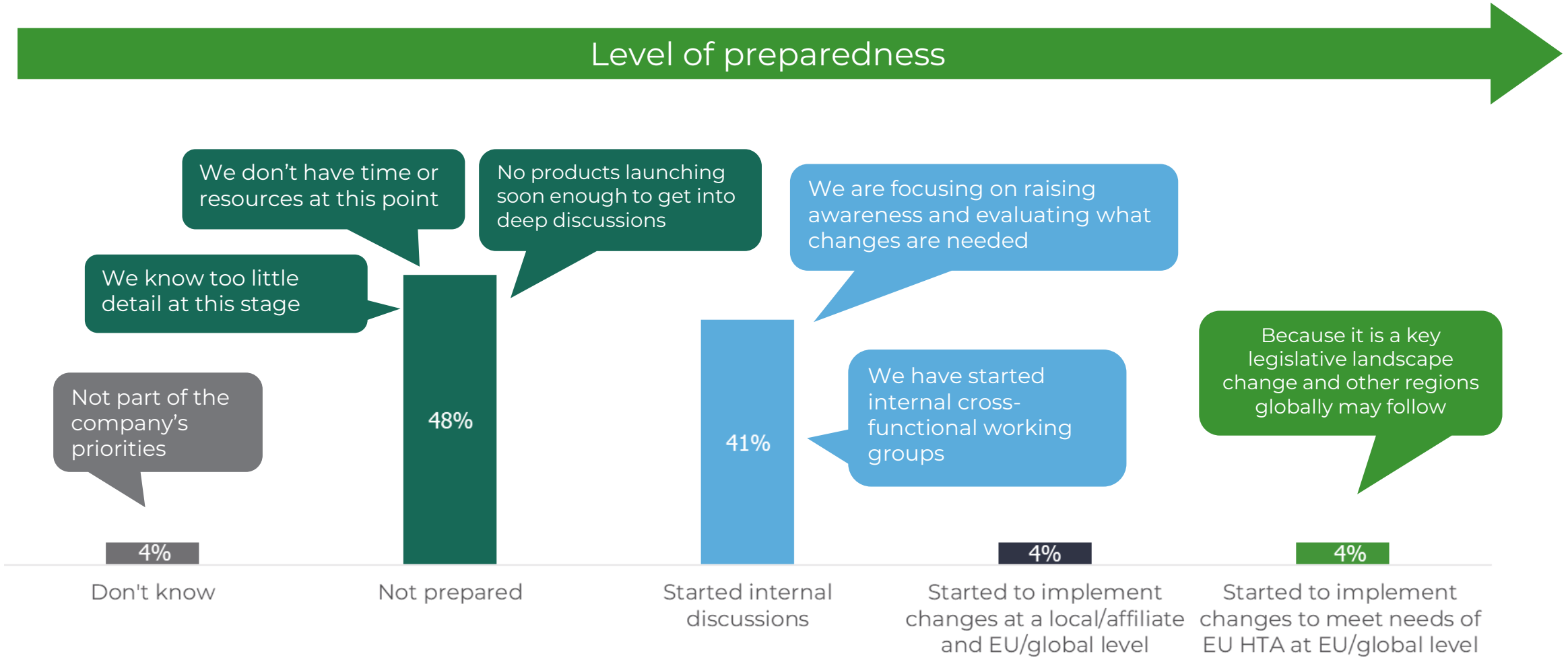


In my company, completing the new EU HTA process will take....



ATMP: Advanced therapy medicinal products; HTA: Health Technology Assessment

The preparations for new processes have not began or are at the internal discussion stage in most respondents' companies

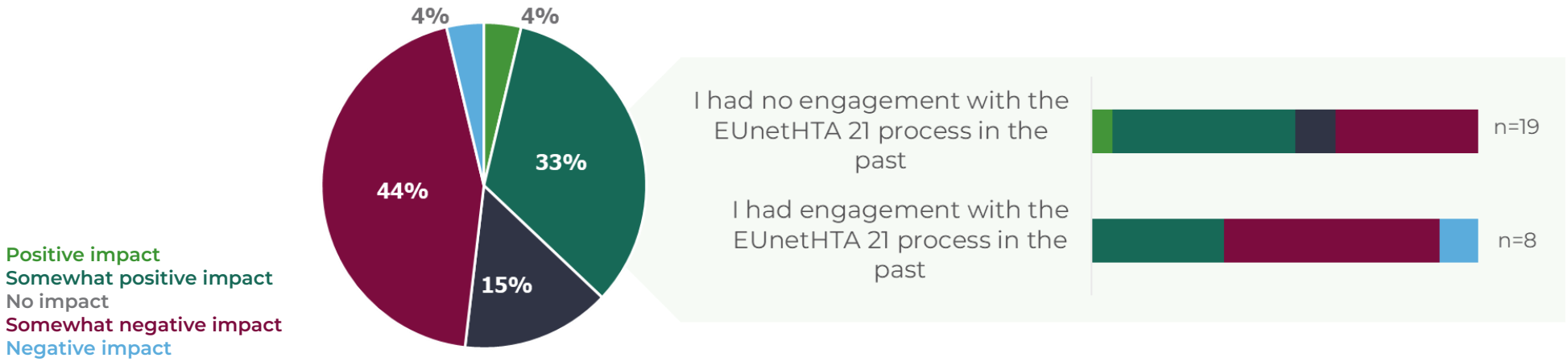


HTA: Health Technology Assessment

Respondents who had previous engagement with EUnetHTA 21 tend to expect more negative outcomes

- 48% of respondents believe the new EU HTA process will have a negative impact on their company. Out of those who have already had engagement wiht the EUnetHTA 21 workstream, as many as 75% shared this negative outlook

What impact do you believe the new EU HTA process will have on the pricing and market access for your company?



HTA: Health Technology Assessment

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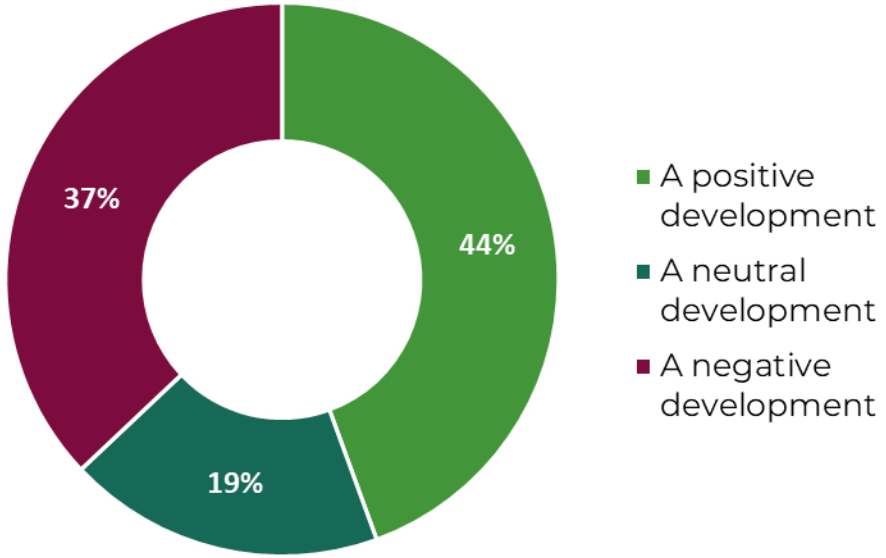
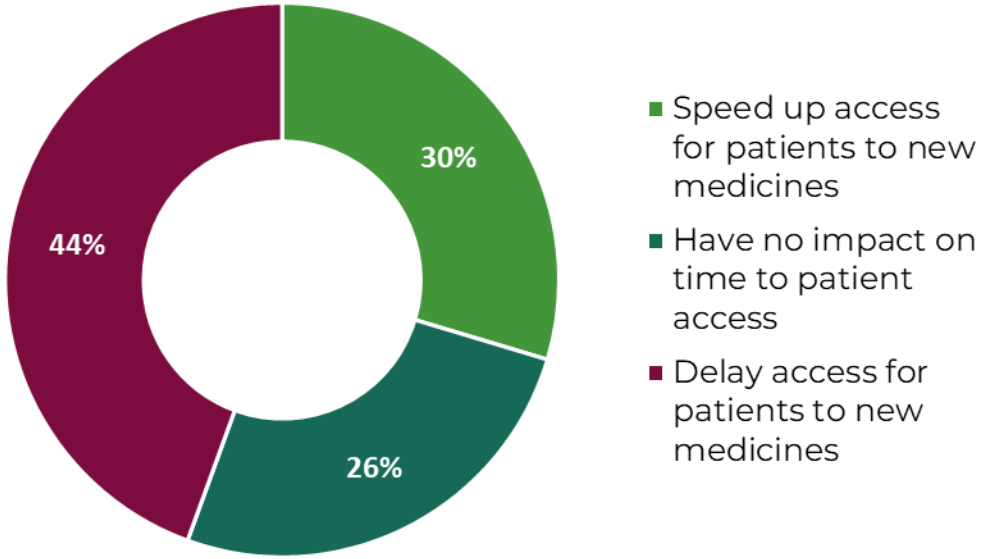
Opinions on whether the EU HTA process will be a positive development and speed up patient access are split

I believe the EU HTA process to be...



The EU HTA process will...



HTA: Health Technology Assessment

Respondents see opportunity in the chance for alignment in evidence requirements and patient access improvements

- Common clinical assessment provides opportunity for better **alignment on currently very heterogenous evidence requirements**
- It could improve information sharing and **availability of innovative technologies** for EU patients
- Patient access could be accelarated in the countries where the **assessment will be the basis for price negotiations**

EU HTA has the potential to become one of the most important changes to the EU Market Access environment in the next decade

Great opportunity if all partners commit to it!

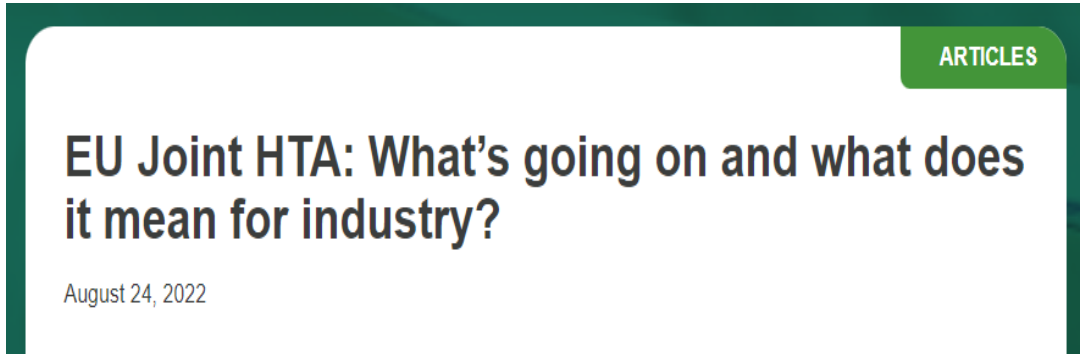
An opportunity for market access colleagues to create an internal dialogue with commercial, clinical and medical colleagues

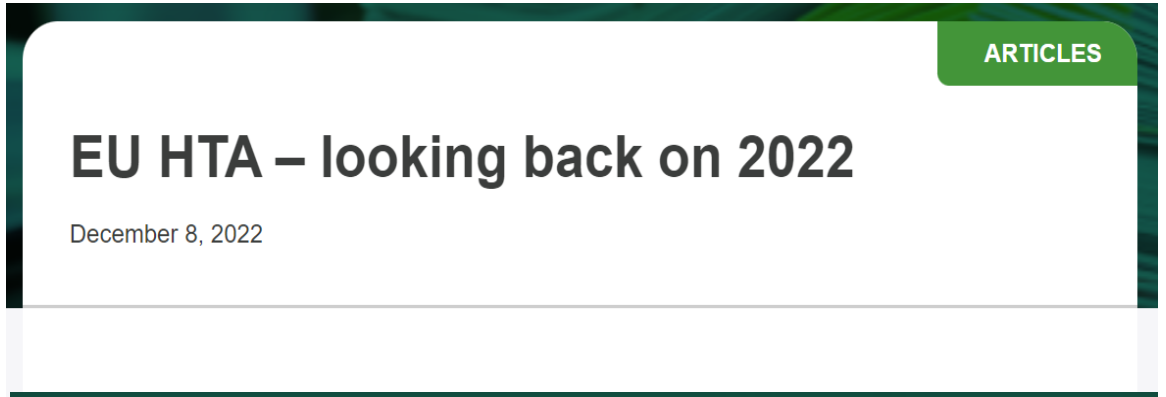
HTA: Health Technology Assessment

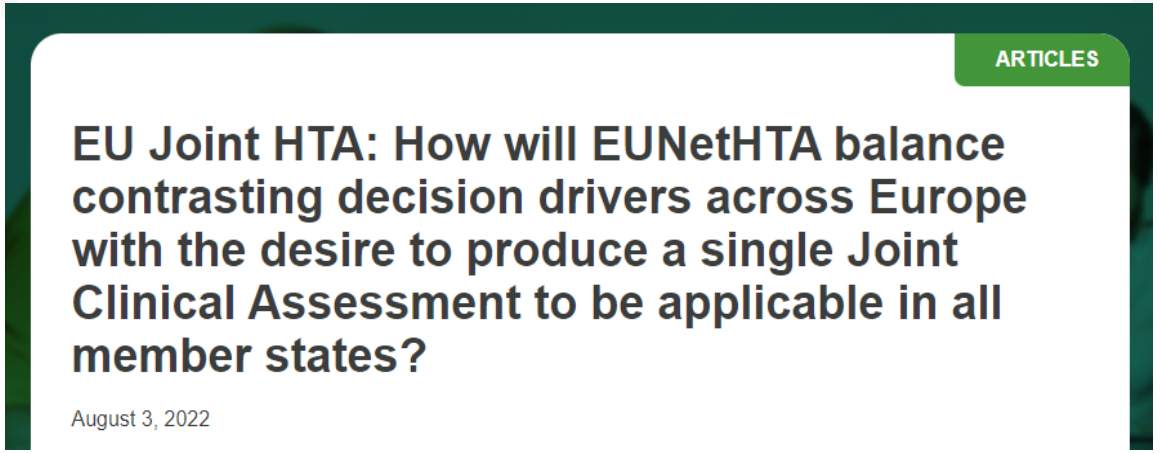
Challenges were identified in both aligning on the evidence requirements and assuring the countries will adhere to it

- Finding and aligning on the evaluation parameters that fit all European healthcare system is considered a main challenge
- Many expect resistance from countries which will aim to maintain their own assessments
- Additional dossiers to meet country-specific demands will be expected
- There is a fear that the process will increase bureaucratic burden on the companies and hinder the patient access

Remap Consulting has written a range of articles on the EU HTA process in 2022







HTA: Health Technology Assessment

Remap Consulting hosted a live webinar to discuss the latest news and updates on the EU HTA process

On Thursday 1st December, Remap Consulting Managing Directors and Market Access Experts, Dr Paul Craddy and Dr Graham Foxon, discussed the EU HTA process news and the findings from the EU HTA survey

Click on the play icon above, or alternatively click here

Thank you

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