

Impact Of COVID-19 On HTA/PRMA of Medicinal Products in Europe: A Payer Perspective

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Conflict-of-Interest

- MME has no conflicts of interest to declare
- Views expressed here are based on feedback of a real-time survey conducted with 8 European payer/payer advisors during a session held in June 2021

Objectives & Methodology

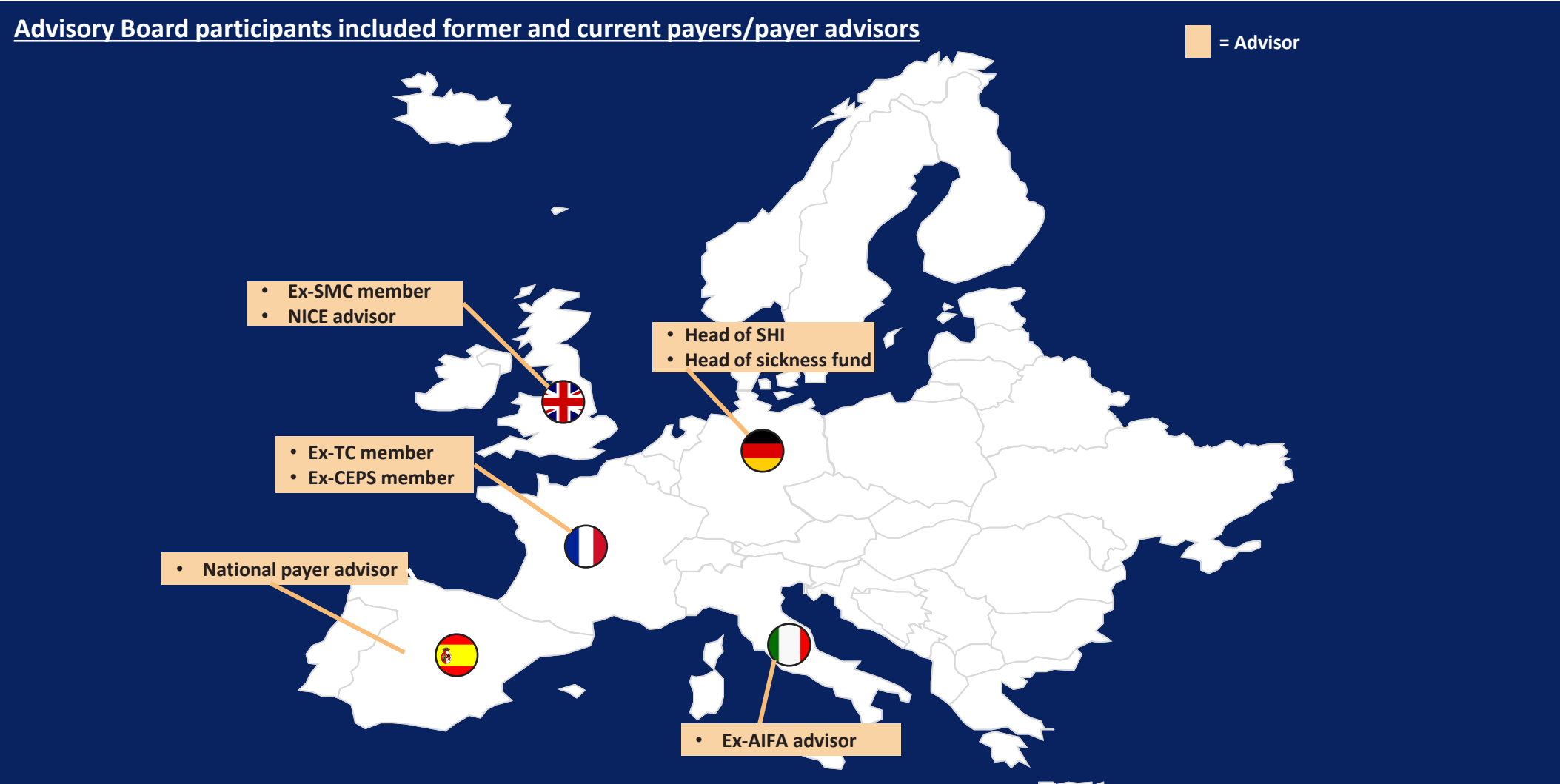
OBJECTIVES

- Assess payer perceptions of COVID-19 pandemic's impact on health systems, focusing on Health Technology Assessment (HTA), pricing, reimbursement and market access (PRMA) of new, branded medicines in the EU4 /UK.

METHODOLOGY

- In June 2021, MME Advisors conducted a virtual, national payer / advisor board with representatives from France (2), Germany (2), Italy (1), Spain (1), and the UK (2) - to discuss key topics within the pandemic's context, such as:
 - Disruption to healthcare systems
 - HTA impact: backlog, re-prioritization, changes in value framework
 - PRMA impact: net price pressure, conditional pricing/RWE and time to market
- Differences and similarities within oncology, rare diseases, Advanced Therapies Medicinal Products (ATMPs) and general medicines were highlighted

MME conducted an advisory board in June 2021; our latest in a *continuing series of advisory boards discussing key PRMA issues*



SMC: Scottish Medicines Consortium; NICE: National Institute for Health and Care Excellence
TC: Transparency Committee; CEPS: Comité économique des produits de santé
SHI: Statutory Health Insurance; AIFA: Agenzia Italiana del Farmaco (Italian Medicines Agency)

Key findings: Changes driven by the pandemic were shifts toward...



Driven by pandemic

Telemedicine

- Payers had differing opinions on whether face to face consultations with physicians would be replaced by telemedicine
 - Potential differences by specialty area and demographic (young vs. elderly patients) were discussed



Driven by pandemic

Logistics/Drug supply security

- Supply chain considerations with focus on research and manufacturing capabilities located in Europe (re-localization of factories and boost for R&D)



Accelerated by the pandemic

Reimbursement of apps, digital health

- Willingness to reimburse digital health is not a consequence of COVID-19 but rather a trend that has been accelerated by the pandemic
- Many health systems, such as Germany, were already moving in this direction



Accelerated by the pandemic

Importance of real world evidence (RWE)

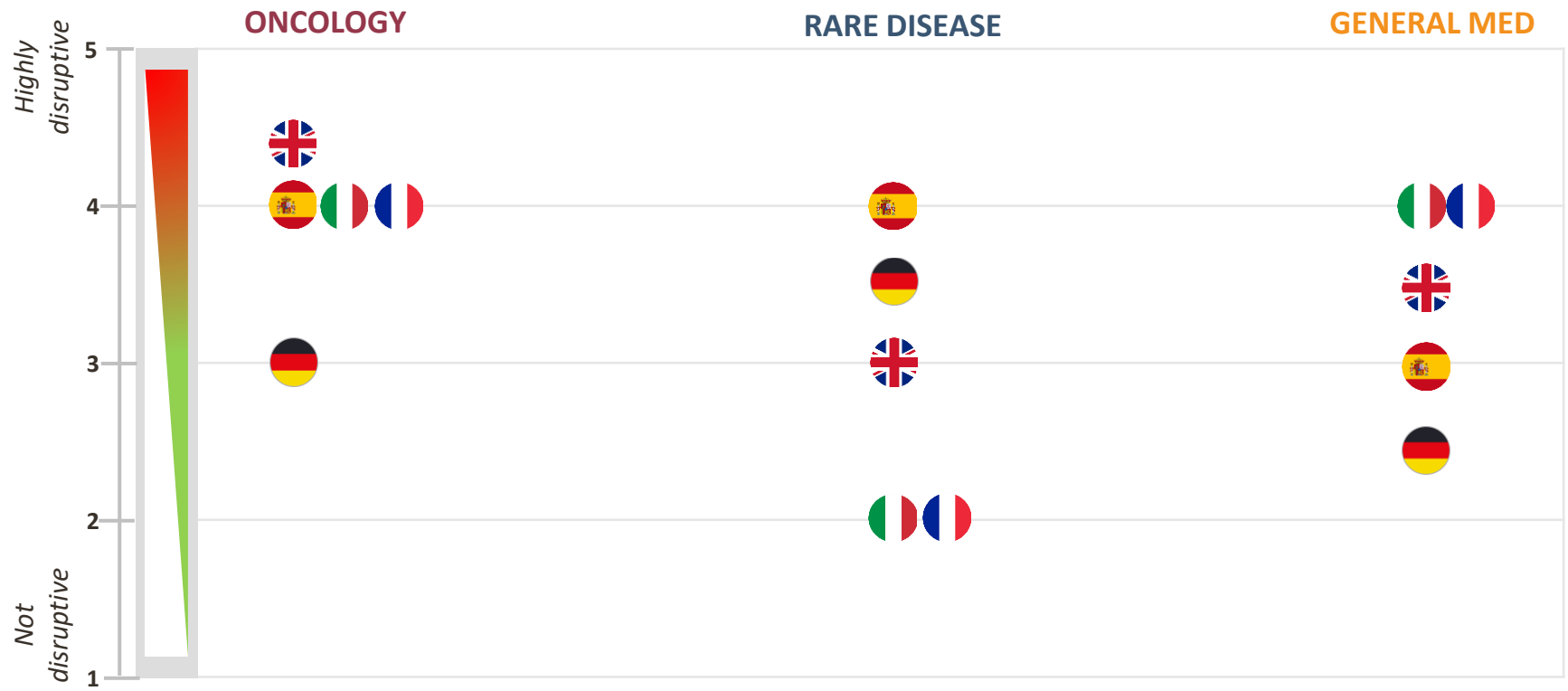
- Higher acceptance of immature data for therapies addressing high unmet need areas with real world evidence collection requirements
- Pandemic has highlighted the potential for rolling reviews although deficiencies in infrastructure for electronic registries is recognized

Example of other changes include discussions ongoing in Germany about restructuring the hospital landscape to have two parallel hospital settings; one for infectious diseases and other for elective surgeries to avoid the backlog that has resulted from the pandemic

Disruption to healthcare systems: COVID-19 pandemic was perceived to be highly disruptive for oncology (less so in Germany)

Mixed responses for disruption to rare disease and general medicine; in France and Italy, rare diseases not believed to be disrupted, whereas in Germany general medicines not disrupted

Oncology diagnosis and surgeries impacted with the focus being on the pandemic and to keep patients away from hospitals; except Germany where oncology care is predominantly delivered in the outpatient setting

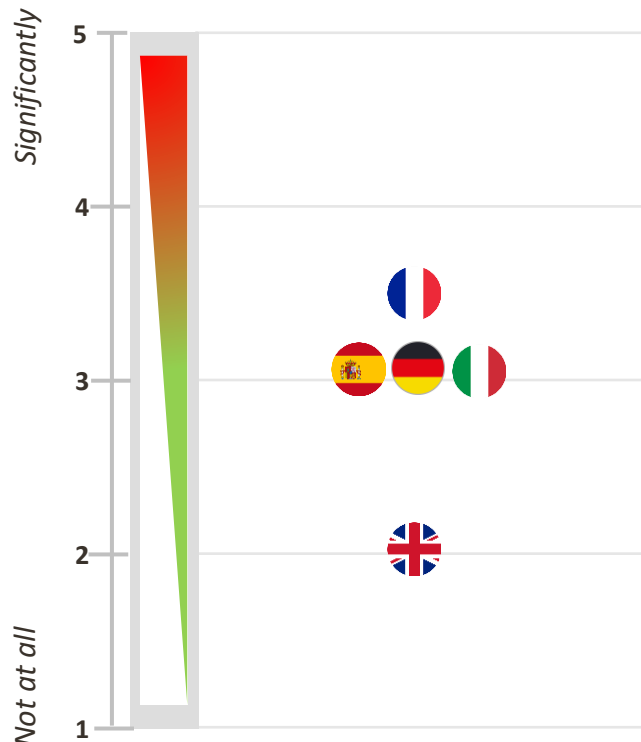


Q3. On a scale from 1 to 5 (1 not disruptive, 5 highly disruptive), how disruptive has the COVID-19 pandemic been on the following therapy areas?: Oncology: Rare disease/ATMPs; General medicine






n=8

Disruption to healthcare systems: Majority of payers did not anticipate a shift in long term priorities or budget cuts post pandemic which manifests differently within the context of individual health systems

Shift in long term priorities



Anticipated budget cuts

France 	<ul style="list-style-type: none"> No budget cuts as per one payer For rare disease/ATMPs and oncology as per other
Germany 	<ul style="list-style-type: none"> No budget cuts as per one payer For rare disease/ATMPs as per other
Italy 	<ul style="list-style-type: none"> No budget cuts
Spain 	<ul style="list-style-type: none"> No budget cuts
UK 	<ul style="list-style-type: none"> No budget cuts as per one payer and For general medicine as per other



Key takeaways

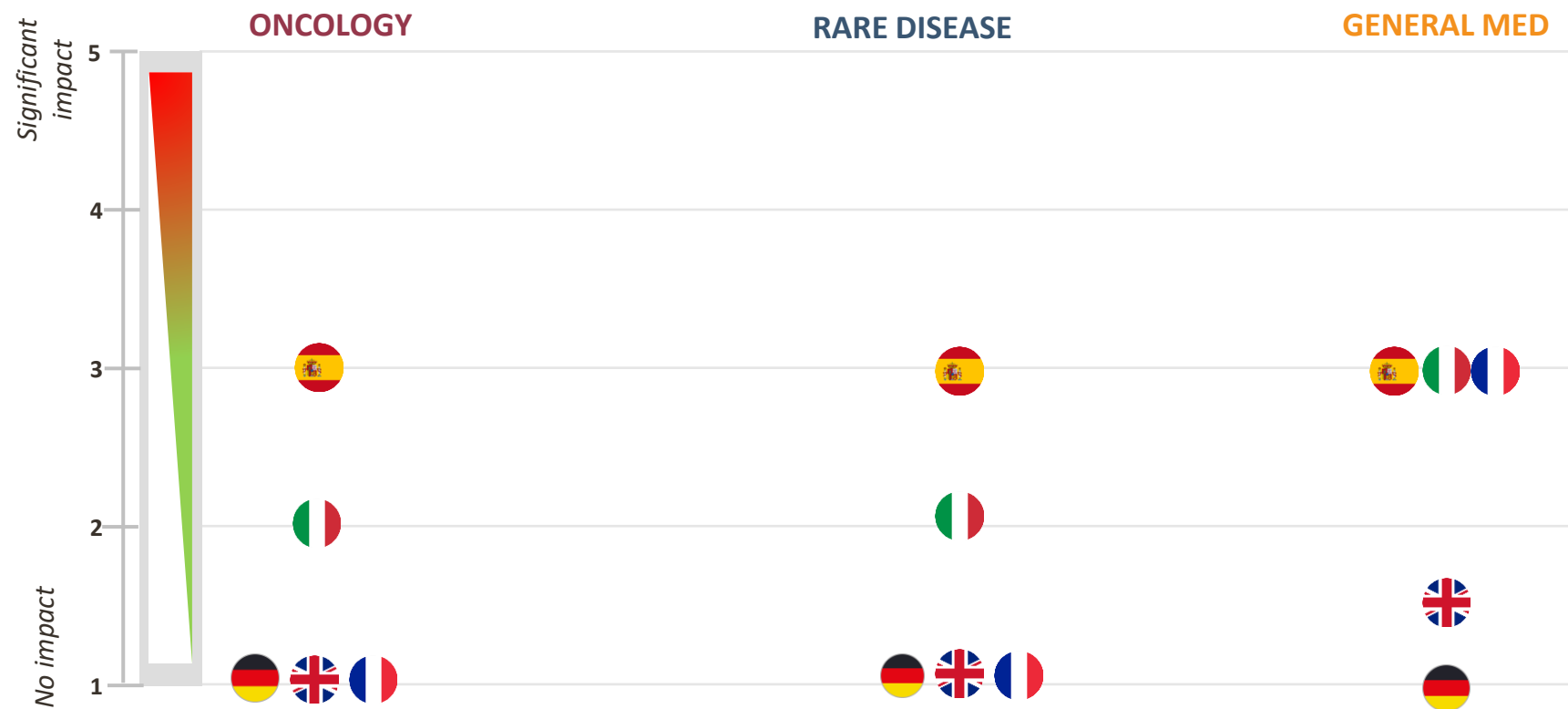
- GDP is the elephant in the room, affordability will be a key issue across countries
- However, it is not so much the impact on budget, but what can be done with it (e.g., making more subtle budget cuts that are not as visible or controversial)
- Impact will be different for central vs regionalized health systems
- Early access schemes such as ATU in France are becoming more stringent

Q4. How much have long-term priorities and approaches to healthcare begun to shift post pandemic? (1=Not at all, 5=Significantly): Shift in long term priorities

Q6. Which of the following therapy areas are budget cuts expected in? (Please check all that apply): Oncology: Rare disease/ATMPs; General medicine; No budget cuts expected

HTA: COVID-19 pandemic impact on HTA backlog has not been significant; majority believed there is no need for therapy areas to be prioritized

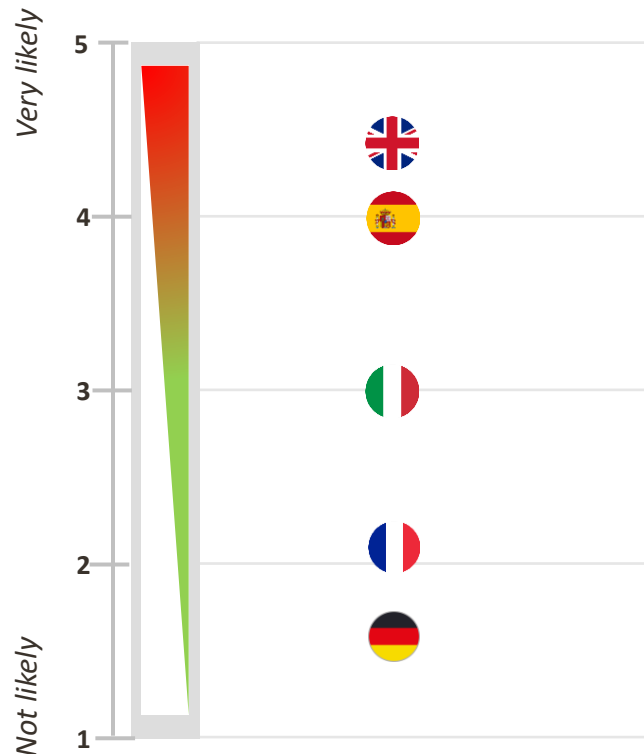
As remote meetings continued, no impact seen in Germany whereas moderate impact in Spain across all categories HTAs for general medicines moderately impacted in France and Italy
 In Scotland, for example SMC introduced abbreviated procedure for “me-too” therapies (e.g., obinutuzumab for CLL)



Q7. On a scale from 1 to 5 (1 no impact, 5 significant impact) how significant do you believe the COVID-19 impact on the HTA backlog has been: Oncology; Rare disease/ATMPs; General medicine
 Q13. Which therapy areas are/will be prioritized for HTA by healthcare authorities in your country to get back on track? (Please check all that apply): Oncology; Rare disease/ATMPs; General medicine

HTA: Likelihood of value framework shifting varied significantly; however, COVID-19 accelerated planned changes but did not drive policy

Shift anticipated in UK and Spain: primarily due to review of NICE processes in the UK and change in HTA methods in Spain. Discussions on reforms ongoing in other countries



Key takeaways

France	<ul style="list-style-type: none"> More request on long term maintenance of effect, more economic value considerations likely
Germany	<ul style="list-style-type: none"> Orphan loophole is likely to close; special framework for oncology combination therapies could be implemented
Italy	<ul style="list-style-type: none"> New AIFA value framework, new P&R dossier guideline in the next 12-24 months, more attention to PE analyses expected
Spain	<ul style="list-style-type: none"> Inclusion of cost-effectiveness in HTA to be incorporated formally
UK	<ul style="list-style-type: none"> Severity of the disease could be considered with revision of NICE methods End of life modifier could be scrapped and replaced by the next 12 months

Q11. On a scale from 1 to 5 (1 not likely, 5 very likely) how likely is it that the value framework for HTA/PRMA will shift in the next 12-24 months?

Q12. What do you believe are likely to be the new value drivers for HTA? Let's discuss.

Time to Market: Anticipated to increase for all therapy areas

Because of economic constraints, Spain anticipated time to market to increase for all therapy areas

Increase anticipated for oncology therapies in Italy, and for rare disease therapies in Germany

Although time to market anticipated to stay the same in the UK, the level of confidential discount negotiated has increased over past 10 years



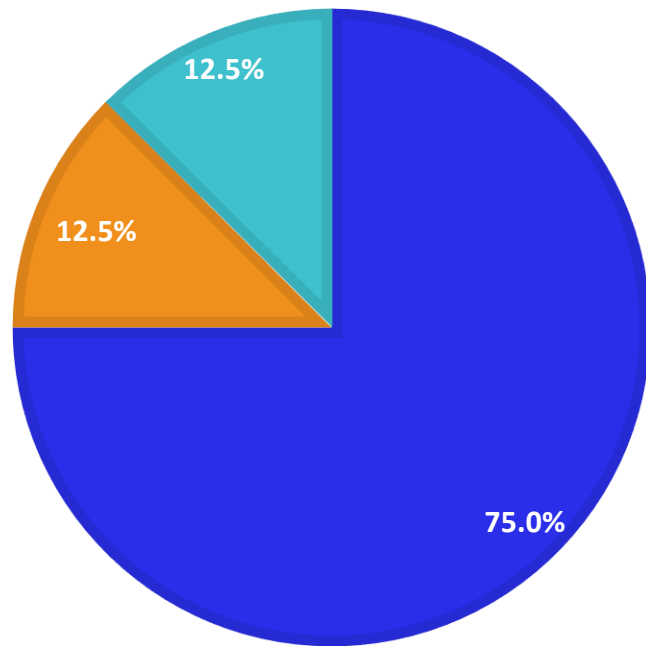
Q14. Do you expect time to market of newly approved branded medicines to increase/decrease post COVID-19? (1=decrease, 3=stay the same, 5= increase): Oncology; Rare disease/ATMPs; General medicine n=8

PRMA: Majority of payers anticipated increased pressure on net prices; however, opinion was divided on increase in conditional pricing/RWE

In France, the difference between list and net price was more than €1 billion in 2019; this is expected to grow for coming years because of affordability issues and higher scrutiny on incremental value of new therapies

INCREASED PRESSURE ON NET PRICE

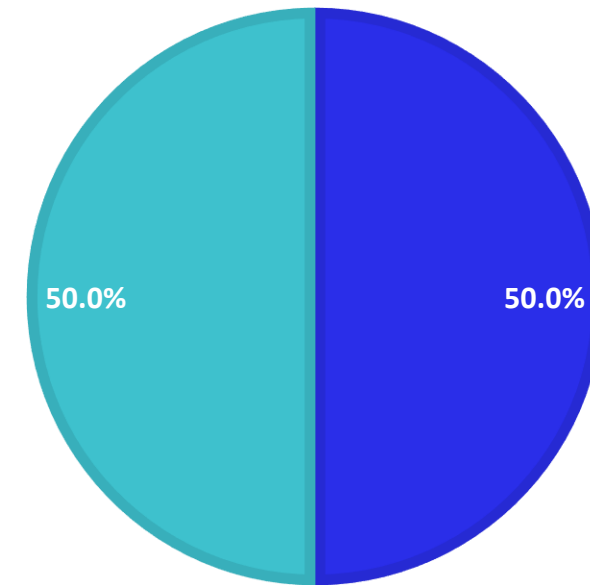
■ Next 12 months ■ More than 24 months ■ No increase anticipated



Only 1 UK payer stated no increase anticipated

INCREASED CONDITIONAL PRICING/RWE

■ Next 12 months ■ More than 24 months ■ No increase anticipated



Q16. Do you expect increased pressure on net prices in (please check all that apply): next 12 months; 12-24 months; more than 24 months; no increase anticipated

Q18. Do you expect increased use of 'conditional pricing agreements' and RWE in: next 12 months; 12-24 months; more than 24 months; no increase anticipated

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Acknowledgement

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MME is planning to conduct another advisory board in Q1 2022 to understand continued impact of COVID-19 on EU PRMA



Thank you

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