FUTURE-PROOFING EUROPEAN PHARMACEUTICAL REGULATORY AND MARKET ACCESS PRACTICES BASED ON LEARNINGS FROM THE COVID-19 PANDEMIC – STAKEHOLDER PERSPECTIVES

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BACKGROUND & OBJECTIVE

COVID-19 pandemic → **Need for** → **Rapid market access** to effective and safe COVID vaccines and therapeutics → Adaptation of **regulatory and market access practices**

Objectives:

- Identify and evaluate **regulatory and market access actions and tools** that were used with the aim of accelerating market access of COVID-19 vaccines and therapeutics in the European context
- Identify **recommendations** that can help to support the future-proofing of regulatory and market access practices in Europe

METHODS

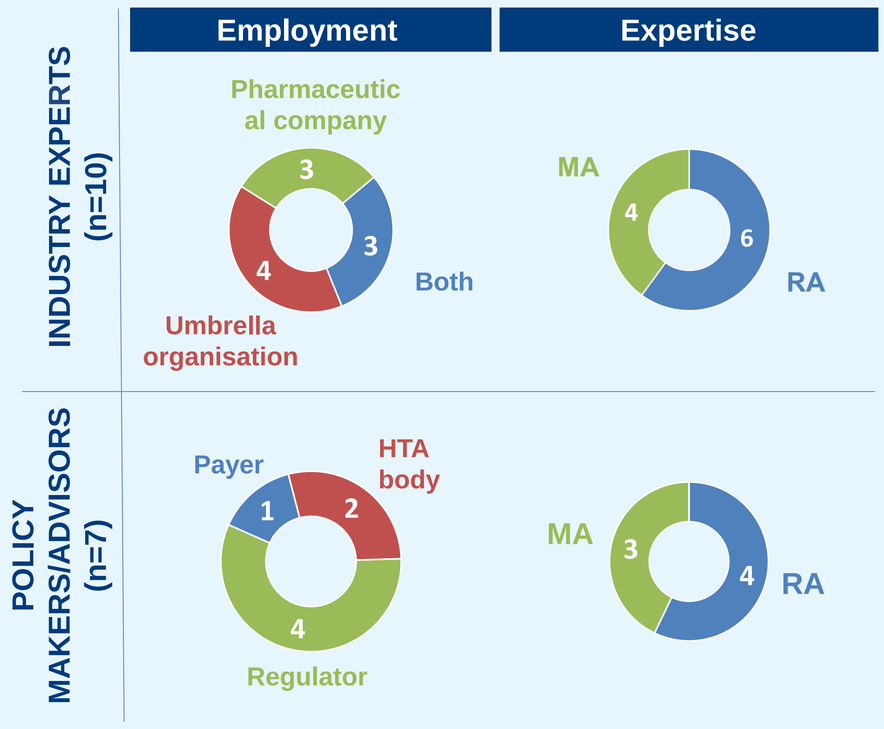
Purposive sampling → Semi-structured interviews → Ad verbatim transcription → Thematic framework analysis

INCLUSION CRITERIA

- ✓ English speaking
- ✓ Expertise in regulatory and/or market access procedures in the EU context
- ✓ Primary and/or secondary experience with COVID-19 practices

RESULTS

Participant characteristics (n total=17)



Regulatory & MA actions and tools applied during the COVID-19 pandemic

Tool	Learnings
1. REGULATORY ACTIONS AND TOOLS	
Rolling review	✓ **High engagement of developers** during the assessment via informal discussions was appreciated by industry participants
	✓ High **flexibility in regulatory assesment timelines** was also favored by industry participants
	✓ Industry participants express the minimalized need for additional regulatory scientific advice
	✗ Policy participants warned of **COI** because of the high involvement
	✗ All participants emphasized the **time- and resource-intensive** nature of this approach
Regulatory reliance	✓ More reliance on European assessments by member states and international authorities is believed by all stakeholders to **safe resources**
	✗ National affiliates expressed doubts on the **quality** of the European assessments and **translatability** to the national setting
2. MARKET ACCESS ACTIONS AND TOOLS	
Joint Procurement	✓ Industry participants favoured joint procurement as it safes **resources** for the applicant
	✓ Policy experts gave the higher negotiating power as an advantage
	✗ Quality of the negotiation was questioned by national HTA experts
Living HTA documents	✓ HTA assessment documents were updated ad hoc, providing stakeholders with the most recent data
	✓ This was enabled via **collaboration** between HTA bodies and led to efficiency gain in terms of resources

Recommendations

1. Industry experts expressed that they would appreciate **higher levels of engagement** and the **increased flexibility** in assessments that were applied during the pandemic to be implemented on a wider scale, in day-to-day practice
2. The increased **alignment** between decision-makers and **harmonization** of regulatory, HTA, and payer practices was identified generally by all participants as favorable
3. Policy experts expressed the need for a good **prioritization & resources allocation system**

ABBREVIATIONS

COI: Conflict of Interest, EU: European Union, MA: Market Access, RA: Regulatory Affairs, HTA: Health Technology Assessment

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CONCLUSION

Stakeholders identified several lessons learned during the COVID-19 pandemic which can be build upon to improve the current regulatory and market access framework for vaccines and therapeutics in Europe. More specifically, based on study findings we advance the following areas of focus:

- **Increasing flexibility in assessment procedures**
- **Engaging stakeholders in regulatory and MA practice**
- **Developing a prioritization system**
- **Harmonizing decision-making procedures**