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Sample Questions for Payer Interviews in EU3, France

For Current Therapies

Q1. We understand that drugs awarded an ASMR I to III and/or drugs with a significant budgetary impact must undergo pharmacoeconomic evaluation.

- How do the pharmacoeconomic data impact the pricing and reimbursement decisions for these therapies?

Q2. The indication [XX] is not classified as an affection de longue durée (ALD; long term illness).

- How does the lack of ALD status or deficit in reimbursement impact physician prescribing of therapies for this indication?

Q3. Do [[indication]] patients represent a substantial burden to the French healthcare system? Do you think there are many patients with [[indication]] that go undiagnosed in France, or is there a good screening program in place?

- Will it become harder for patients to have access to therapies to treat [[indication]] in the future?

Q4. What treatment guidelines do physicians follow for [[indication]] (i.e. HAS national guidelines, ALD guidelines, regional guidelines, local/hospital guidelines)?

- How strictly must physicians adhere to guidelines to ensure reimbursement for [[indication]] patients?

Q5. To what extent are physician prescribing practices monitored? At which level does the monitoring take place (national, regional, local/hospital) and how is it done?

- Are there any penalties for nonadherence? How do you think the monitoring of physician prescribing practices may change over the next few years?

Q6. Are drugs targeted to specific population subgroups (e.g., XX) more likely to receive a more favorable SMR and ASMR rating?

Q7. What do you think is the average discount to list price that hospitals are able to get on [[indication]] therapies? To what extent do these discounts affect the inclusion of these therapies in hospital formularies? How importantly does cost factor into physicians' first-line therapy choice?

Q8. In its National Health Strategy, France aimed for 80% biosimilar penetration by 2022. How or by which means do you expect France to achieve its 80% goal of biosimilar penetration?

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For Emerging Therapies

Q1. **What kind of data is most important for emerging therapies to secure favourable SMR and ASMR ratings?**

- **Will they need head-to-head data? What would they have to show in terms of safety or efficacy to demonstrate additional benefit over current therapies?**
- **What would be the best comparator to use for a new [[XX]] agent? What about for a new [[XX]]?**
- **Two emerging therapies [[XX]] offer extended dosing compared to [[XX]]. How important is dosing frequency from a payer perspective, assuming that efficacy and safety are at least comparable?**
- **How important is pharmacoeconomic data for the drug evaluation?**
- **How important is real-world data (RWD)? Do you anticipate increased use for RWD in the pricing and reimbursement process in the future?**

Q2. **What are your expectations for the SMR and ASMR rating for therapies [[ ]], presuming each one gains marketing authorization in Europe?**

- **Which one of the emerging therapies do you think has the greatest potential for a high price?**
- **In your opinion, will any of these drugs be deemed NOT reimbursable?**

Q3. **Do you anticipate any payer-imposed prescribing, dispensation, and/or monitoring guidelines that could restrict the use of any of these drugs?**

Q4. **Do you expect any of the emerging therapies to be subject to managed entry agreements (MEAs), such as risk-sharing or price-volume agreements?**

- **Will these improve the likelihood of new therapies receiving reimbursement?**
- **Is there a preferred design for an MEA in France?**

Q5. **Are there any upcoming healthcare reforms or changes in the pricing and reimbursement system in France?**

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