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Sample Questions for Payer Interviews in EU3, UK

For Current Therapies

Q1. Do [[indication]] patients represent a substantial burden to the UK healthcare system? Do you think there are many patients with [[indication]] that go undiagnosed in UK, or is there a good screening program in place?

• To what extent are the costs of [[XX]] treatment reimbursed for patients? Will it become harder for patients to have access to therapies to treat [[XX]] in the future?

Q2. What treatment guidelines do physicians follow for [[XX]] (i.e. NICE guidelines, hospital/CCG guidelines)? How strictly must physicians adhere to NICE guidelines to ensure reimbursement for [[XX]] patients?

- Are specialists authorized to treat [[XX]] patients with approved products outside of NICE guidelines?
- Do CCGs ever impose additional restrictions on the prescribing of [[XX]] therapies, outside of those in • the NICE guidelines?

Q3. 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 non-adherence? •
- How do you think the monitoring of physician prescribing practices may change over the next few years?

Q4. Are physicians able to prescribe [[XX]] off-label for [[XX]] in the UK? If so, how?

What are the funding sources available for off-label use?

Q5. Are drugs targeted to specific population subgroups (e.g., XX) more likely to receive a more favorable review?

• Do you think there is a need for drugs that are administered by alternative modes of delivery?

Q6. Please explain how [[XX]] therapies are reimbursed.

• Do they fall under the payment by results (PbR) tariff between the hospital and the NHS or is the burden on the CCG to cover the costs?

Q7. What do you think is the average discount to list price for [[XX]] therapies? To what extent do these discounts affect the inclusion of these therapies in hospital formularies?

Do these discounts vary by CCG? How importantly does cost factor into physicians' first-line therapy • choice?

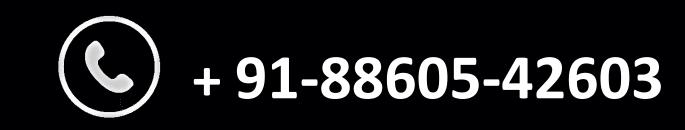


Q8. What policies are currently in place in the UK to encourage the prescribing of biosimilar therapies? What will be the impact of biosimilar availability for new costly branded [[XX]] therapies? Will physicians be required to prescribe biosimilars over branded [[XX]] therapies?





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Sample Questions for Payer Interviews in EU3, UK

For Emerging Therapies

Q1. What kind of data is most important for emerging [[XX]] therapies to secure a favourable NICE review?

• 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?

• Two emerging agents [[XX]] are expected to offer extended dosing compared with the current agents for the treatment of [[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 NICE recommendations for each therapy, 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 using any of these drugs?

Q4. Do you expect any 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 the UK?

Q5. Are there are upcoming healthcare reforms or changes in the pricing and reimbursement system that we have not already discussed?





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