

When and How to Commercialize your Ophthalmic Drug in Europe

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Shire



Navigating the diversity of the EU markets can be complex

- 28 members states form the European Union
- Wide variety of regulatory and healthcare systems
- Primarily single payer with different pathways for reimbursement by country





Early focus on your EU regulatory strategy can have significant payoff

- Does your study design take into account requirements of EU regulators?
 - selection of endpoints, study duration, etc.
- What is the standard of care in your priority markets?
- Which submission process is most appropriate?
 - centralized vs. decentralized submissions





Reimbursement pathways can vary greatly across the EU

- What evidence will HTAs and budget holders require for pricing and reimbursement?
- How might your indication impact reimbursement?
- What is your optimal launch sequence?



MARKETING STRATEGY

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Meeting
5:30 PM

Wed
12/10
5:30 PM



Important to design a go-to-market model that scales across countries

- Are you investing appropriately in pre-launch activities?
- Do you have a brand that crosses borders and cultures?
- How do you design a launch strategy that can be driven globally but executed locally?



“By failing to prepare, you are preparing to fail.”

— [Benjamin Franklin](#)



THANKS!

Any questions?
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