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
• What evidence will HTAs and budget holders require for pricing and reimbursement?

• How might your indication impact reimbursement?

• What is your optimal launch sequence?
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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