

Elevating the Patient Voice in Generic Drug and Biosimilars Development

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Importance of Patient Voice in Generics and Biosimilars

Lessons to Learn from Innovative Drug and Biologic Development and Regulatory Decision-Making*

Focus on Patient-Relevant Outcomes

Shift focus beyond just clinical outcomes to a more comprehensive understanding of how a drug impacts a patient's daily life, health, and quality of life, e.g., device considerations.



Address Patient Concerns

Patients can voice concerns about differences in inactive ingredients (like flavors or colors) or changes in a drug's physical form (shape, size), which can affect their willingness to take the medication

Help Prioritize Which Generics to Develop

Patient input can help identify which generics, particularly complex generics, would be most meaningful to patients and help address gaps in the market.

Manage Patient Expectations (Improve Medication Compliance)

Involving patients and patient advocacy groups (PAGs) in the decision-making process can better manage patient expectations and reduce the likelihood of patients discontinuing their medication due to perceived changes

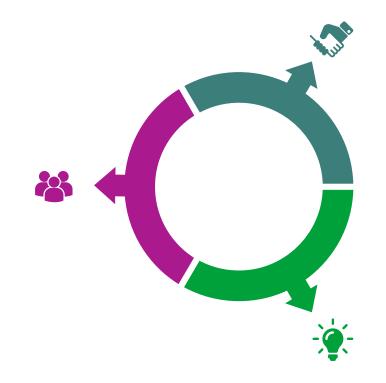


Integrating Patient Voice in Generics and Biosimilars

Inform Development and Regulatory Review

Advocacy Groups

Patient advocacy groups and organizations play a key role in bringing patient perspectives to the table and can provide valuable insights to both regulators and companies.



Pharmaceutical R&D

Companies can seek patient input to improve their research and development processes. This can include qualitative research like interviews or focus groups, and quantitative methods to gauge patient preferences.

Regulatory Input

Regulatory bodies like the FDA can seek patient input to understand what is important to patients regarding health interventions.



Q&A





THANK YOU

