Abstract

Biosimilars are crucial therapies for chronic and life-threatening diseases. Indonesia presents a substantial market for biosimilars, with a large population of 280 million and the largest economy in Southeast Asia. Nevertheless, biosimilar development in Indonesia still encounters various obstacles. This study aims to identify and analyze key challenges in biosimilar development in Indonesia and provide strategic insights for industry stakeholders and regulators. This study employed a qualitative design with a hybrid thematic analysis approach through semi-structured interviews with three key informants: two industry players and one representative from a regulatory authority. Data were analyzed based on initial themes from the literature and findings emerging from the interviews.

The interviews with these informants identified six key challenge groups: (1) financial challenges, including high capital requirements, low investor confidence, and uncertainty about reimbursement; (2) regulatory challenges, such as complex procedures, long approval times, and the absence of prioritization mechanisms; (3) market access challenges due to price competition, volume uncertainty, and limited BPJS coverage; (4) human resource challenges related to limited biotechnology expertise and lengthy adaptation processes; (5) technical challenges, including the lack of certified laboratories and animal testing facilities; and (6) challenges from short-term government programs that are not aligned with the biosimilar development cycle.

The conclusion of this study is that efforts to accelerate biosimilar development require an integrated strategy that includes strengthening regulations, long-term investment, developing technical infrastructure, and enhancing human resource capacity to enable Indonesia to increase its independence and competitiveness in the biosimilar industry.

Keywords: biosimilar, biopharmaceuticals, regulation, industry challenges, Indonesia