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Payers and Biosimilars Challenges in Oncology Field in Mena Region Policy Analysis

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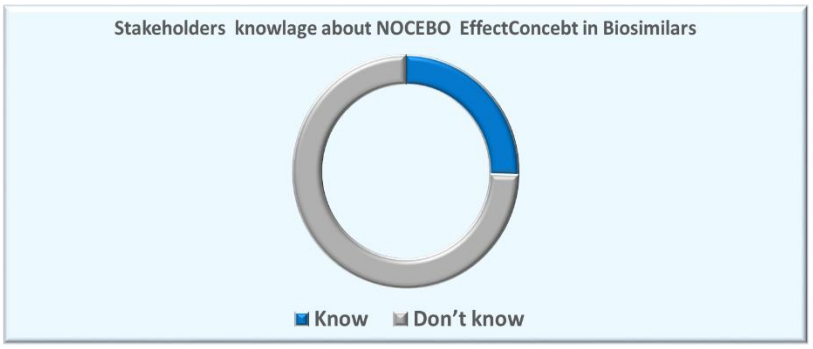
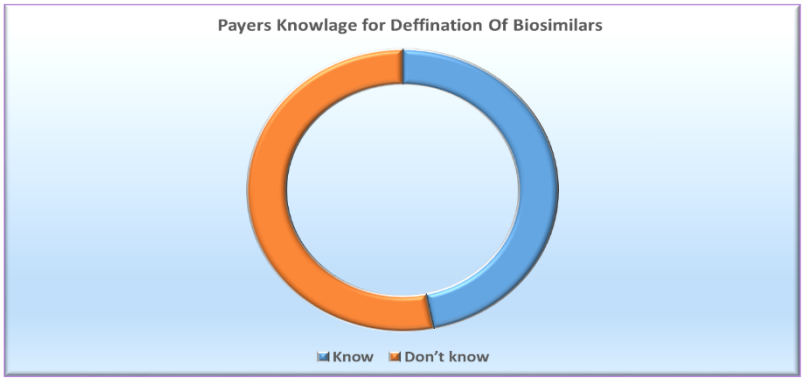
Background

With the presence of concept of Biosimilar products at last decade which defined by WHO as (A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product.) interchangeability concepts for Biosimilars was raised by the payers to develop multidisciplinary tools for policy analysis which is the main core of HTA. The main objective for this study is to determine the roles that can HTA body play for Biosimilar products starting from regulatory step finished by decision for reimbursement. Methods in Oncology field in MENA Region

Integration between A systematic literature review &Descriptive analysis of (FDA, WHO EMA, local guidelines and local data from regulatory bodies for efficacy, safety, quality) for Biosimilars & ISPOR guidelines for HTA .Interviews were conducted with Key stakeholders for health system contain validated Questioner in(Egypt, Tunisia, Jordan, Algeria , Saudi Arabia. United Arab Emirates. And industry representative.

Results





main five Elements influencing decision making in Oncology field was mentioned below based on analysis

Conclusion

Based on previous experiences from countries for starting switching to Biosimilars and return back in immunology. Biosimilars should not be treated as generic products In terms of HTA there is a need to conduct a selection criteria specialized for Biosimilars, pricing process should be on case by case basis due to the nature of technology of Biosimilars The need for evidence base data for switching from innovator products to Biosimilars should be mandatory during marketing authorization process An integration between regulatory body and HTA should be initiated. As both bodies differ for their prospective and they need to integrate in order to minimize time consumption and unifying concepts for Biosimilars. Effective assessment and evaluation for Biosimilars the comparator of HTA should be different standard of care may and may be not contain the reference product or second generation of Biosimilar.

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