

# ESTABLISHING THE VALUE OF EMERGING BIOSIMILARS

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## INTRODUCTION

- The development and launch of biosimilars for blockbuster therapies such as Enbrel, Humira, MabThera, and the potential of biosimilars for orphan biologics is dramatically changing the market access landscape for these treatments
- The stakeholders involved and their relative influence in determining treatment selection is shifting
- The ultimate balance of decision-making power will vary depending on the therapy area, mode of administration, care setting, and country specific funding mechanisms

## OBJECTIVES

1. Understand the evolving market access mechanisms for monoclonal antibodies as biosimilar versions become available
2. Identify the key stakeholders influencing access decisions
3. Determine the biosimilar value drivers and education needs across the major stakeholder groups

## METHODOLOGY

1. This research focused on immune-mediated disorders, oncology, and rare diseases
2. A large sample of stakeholders (n=-800) were engaged, including clinician specialists, pharmacists, purchasers, payers and patients from across Europe and the U.S.
3. Navigant conducted in-depth qualitative interviews with ~400 stakeholders plus a qualitative survey with ~400 respondents to gain an understanding of the current landscape and future expectations for biosimilars

## RESULTS

- The arrival of biosimilars for monoclonal antibodies is changing the roles and influence of stakeholders determining market access. More of the decisions driving product selection will be made upstream of the prescribing clinician. As biosimilars are launched, manufacturers of the incumbent originator and novel biosimilar entrants will need to focus efforts on demonstrating value to newly empowered stakeholders
- The extent of upstream decision-making will differ depending on drug procurement and funding channels. These will be strongly driven by 1) the markets overall approach to drug funding, and 2) the disease indication
- Major EU markets can be categorised into four archetypes based on the degree of centralisation in drug funding and purchasing
- With increased numbers of biosimilars, the influence of the patient and of the prescribing physician will decrease across all markets as payers are able to leverage competition to drive down costs

### PHYSICIAN DRIVEN 🇩🇪

- Treatment selection for **immune-mediated diseases** is in the hands of the clinician. Subcutaneous biologics given in the outpatient or home setting are subject to few explicit restrictions. Biosimilar competitors will enable payers to more aggressively contract for discounts and rebates. The opportunity for cost savings will spur payers to more directly influence product selection, reducing clinician autonomy
- Clinicians report few restrictions on product choice for **oncology treatment**. The availability of biosimilar options will enable payers to contract with manufacturers for volume based discounts. The results of these contracts will limit the brands available in the hospital
- Access to treatment for **rare diseases** is usually centralised to a few select institutions and funding for high cost treatments is approved on an individual patient basis. The potential for even modest cost savings from biosimilars will empower the national payer to determine product selection

### COST EFFECTIVENESS 🇬🇧

- Physicians are required to prescribe the most cost-effective product. This is most apparent with anti-TNF selection for **immune-mediated diseases** where regional payers will mandate use of a preferred product which will persist with biosimilar availability
- **Oncology biologics** are reimbursed centrally by the national payer with the potential for biosimilar cost savings, either budgetary responsibilities and or incentives for cost savings will be shared with regional or local payers to encourage uptake
- Access to high cost drugs for **rare diseases** is tightly controlled by the national payer. No changes are expected with biosimilar availability

### BUDGET IMPACT 🇮🇹

- Budgets for the treatment of **immune-mediated diseases** and **oncology** are managed at the regional and hospital level. Clinicians must prescribe within budgetary constraints which not only limits their product options, but may also restrict the number of patients they may treat. Biosimilar availability will increase the potential for payers to extract cost savings and will lead them to exert further control over funding and treatment selection. Simultaneously those cost savings may also enable more patients to be treated
- Treatment of **rare diseases** is already limited to a few select specialised centers where the budget for treatment is tightly controlled. This degree of centralisation will persist with biosimilar availability

### NATIONAL TENDER 🇸🇪 🇩🇩 🇩🇩

- In these markets, when there is no competition, payers have absolute decision making for providing access or not. Clinicians have prescribing freedom for any available product
- Biosimilar availability will enable these markets to design and field a competitive tender. As a result, product availability will be determined by the tender winners and clinician choice will be further restricted

### CURRENT LEVELS OF INFLUENCE OVER PRODUCT SELECTION

Stakeholders	Market Archetype and Indication											
	Physician Driven			Cost Effectiveness			Budget Impact			National Tender		
	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.
Patient												
Clinician	High	High	High	Low	Low	Low	Low	Low	Low	High	High	High
Hospital Admin/ Pharmacist	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Regional/ National Payer	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Levels of influence Low Medium High

### FUTURE LEVELS OF INFLUENCE OVER PRODUCT SELECTION

Stakeholders	Market Archetype and Indication											
	Physician Driven			Cost Effectiveness			Budget Impact			National Tender		
	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.	Immuno	Onc	Rare Dis.
Patient												
Clinician	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Hospital Admin/ Pharmacist	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Regional/ National Payer	High	High	High	High	High	High	High	High	High	High	High	High

## CONCLUSIONS

- These findings highlight the diversity of stakeholders and some of the anticipated changes that are likely to arise from the increasing number of biosimilars
- Originators and biosimilar manufacturers need to identify the future decision maker and there is a need for greater awareness of the different value needs and expectations for each payer stakeholder
- Ensuring access in this changing field will require a tailored approach to communicate value to key influencers and stakeholders along the biosimilar value chain