

EXPLORING BIOSIMILAR MARKET ACCESS CONSIDERATIONS ACROSS EUROPE



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Introduction/objective

- ▶ Biosimilars are becoming more widely available across Europe, with many payers at each level involved in decision-making regarding their market access.
- ▶ Despite recognition of the benefits of biosimilars (reducing cost of treatment thus freeing up resources to treat more patients, maximising health care outcomes and enabling cost savings to support new innovation) decision-making and access processes are still finding their place within each country's healthcare system.
- ▶ This study investigates the local market access needs of European countries in relation to biosimilars, in order to identify and understand the key criteria which currently drive payer decision making.

Methods

- ▶ The research incorporated insights gathered through a targeted secondary literature review across 15 European markets, which identified relevant recent biosimilar publications and country-specific biosimilar policy documentation.
- ▶ Supplementary payer research across was also conducted to address any evidence gaps in payer decision-making.
- ▶ Key factors were assessed including, stakeholder roles, decision-drivers and pricing and market access requirements, which allowed us to identify clear payer archetypes across countries and critical success factors for biosimilar launch.

Results

- ▶ Through comparing and contrasting stakeholder roles (Table 1), decision-drivers (Table 2) and access requirements (Figure 1), 4 distinct payer archetypes were identified: single-country tender, regional contracting/ tendering, local (hospital contracting/tendering) and retail. The assessment allowed for critical success factors to be defined in terms of strategies/ tactics that pharmaceutical companies 'should and shouldn't do'.

Table 1: Stakeholder influence on access by payer archetype

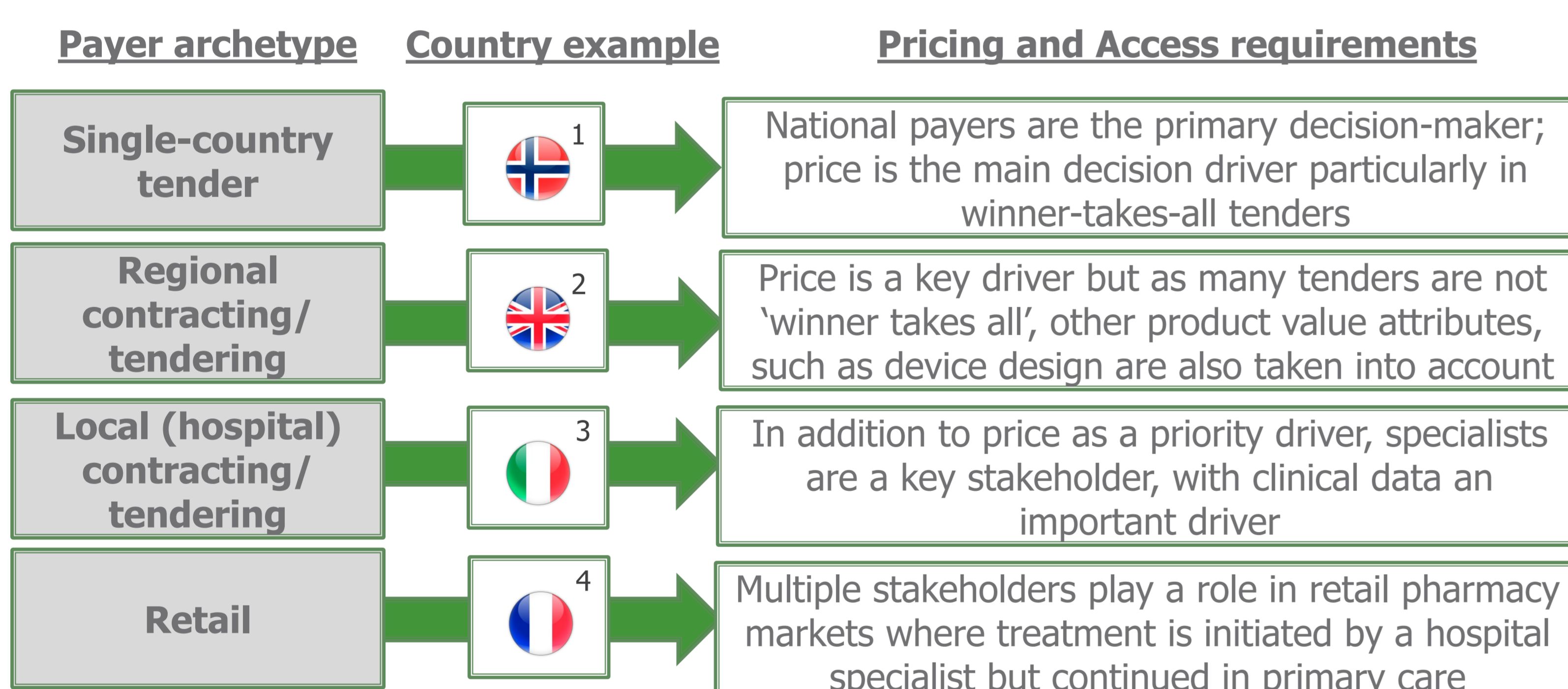
Stakeholder influence on access	Payer Archetypes			
	Single-country tender	Regional contracting/ tendering	Local (hospital) contracting/ tendering	Retail
National body (PMA)	●	◐	◐	●
Regional body	○	●	◐	◐
Hospital procurement	◐	◐	◐	◐
Hospital pharmacist	○	◐	●	◐
P&T committee	◐	◐	◐	◐
Hospital specialist	◐	◐	●	◐
Retail pharmacist	○	◐	◐	◐
Retail prescriber	○	◐	◐	◐

Table 2: Decision-drivers by payer archetype

Decision-driver influence on access	Payer Archetypes			
	Single-country tender	Regional contracting/ tendering	Local (hospital) contracting/ tendering	Retail
List price	○	◐	○	●
Net price	●	●	●	◐
Product value	◐	●	●	◐
Tenders	●	◐	◐	○
Gain-share agreements*	○	◐	◐	◐
Usage guidelines	○	◐	◐	◐
Biosimilar prescription quotas	○	◐	◐	◐

*Decision-driver relevant for specific payer archetypes and countries (UK and France) only

Figure 1: Differences in key access requirements across payer archetypes



References represent examples of countries which fit into each archetype

Figure 2: Example 'critical success factors' by payer archetype

Payer archetype	'Should do'	'Shouldn't do'
Single-country tender	<ul style="list-style-type: none"> • Ensure net pricing strategy takes into account competitive environment • Learn from competitor 'good practise' (purchasing/ procurement systems) 	<ul style="list-style-type: none"> • Rely on tender win alone to drive uptake • Discount net price to a level which jeopardises profitability
Regional contracting/ tendering	<ul style="list-style-type: none"> • Map tender landscape • Target late adopters 	<ul style="list-style-type: none"> • Price for one tender • Risk loss of credibility by overpromising across regions
Local (hospital) contracting/ tendering	<ul style="list-style-type: none"> • Engage early and often • Optimise value proposition by emphasising additional services 	<ul style="list-style-type: none"> • Target early adopters • Use complex outcomes based contracting agreements
Retail	<ul style="list-style-type: none"> • Check for list price flexibility • Target initiating specialists leading treatment choice 	<ul style="list-style-type: none"> • Reduce list price to detriment of reference pricing • Disregard pharmacy switching guidelines

Discussion and conclusions

- ▶ Although European payers welcome biosimilars, differences in their assessments and access requirements mean that pharmaceutical companies need to adapt their access approaches in order to support positive access decisions.
- ▶ The use of payer archetypes can help in the development of effective, tailored local market access strategies.
- ▶ Recognising the combination of relevant payer archetypes within each country and the strategies and tactics which may be used to leverage key decision-makers can further add further granularity to local access plans.
- ▶ Highly tailored local access strategies could support many components of the access process such as, successful interactions with key stakeholders, identification of ideal value proposition for negotiations (i.e. product value levers vs use of price as a lever), reducing focus on price to ensure 'sustainability', optimal contracting arrangements with regional/ local payers and optimal tender wins or tender shares.

References

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- ² NHS England, Commissioning Statement for biologic medicines (including biosimilar medicines). Published September 12th 2017
- ³ Enrico Adriano Raffaelli, FaustoMassimino; Reference Biological Medicines ('originators') and 'biosimilars': Competition and Patient Protection. Italian Antitrust Review
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