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Implications of indication expansions on pricing and reimbursement and differences between EU4 and UK markets

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INTRODUCTION

Sequential launching in multiple indications is becoming increasingly common, especially in therapeutic areas such as oncology and autoimmune diseases. Determining the appropriate price for these multi-indication products is complex as the product's value tends to vary substantial between indications[1]. Understanding the factors considered when determining the product's value and how pricing mechanisms differ across the EU4, and UK is therefore key to a successful launch in a second indication.

OBJECTIVE

To analyse the pricing and reimbursement considerations when launching in a second indication in the EU4 and UK.

METHODS

Relevant scholarly articles, reports, and publications concerning indication expansions, pricing strategies, and reimbursement mechanisms across France, Germany, Italy, Spain, and the United Kingdom were identified and reviewed.

RESULTS

Upon launching in a second indication, it is important to understand how the product's value differs versus the first indication in which the product launched. Factors considered when determining value include:

Added benefit
What therapeutic advantage does the drug provide over current standard of care?

Unmet need
Are there a lack of available treatments or do the current options fail to adequately treat the condition?

Population size
How many patients are likely to benefit from the new drug?

Competitive landscape
How many treatment options already exist for these patients?

Pricing dynamics
What is the net price of the product in the first indication? What is the net price of comparator products?

Chart 1. Impact of value differentiation between first and second indication on product price potential

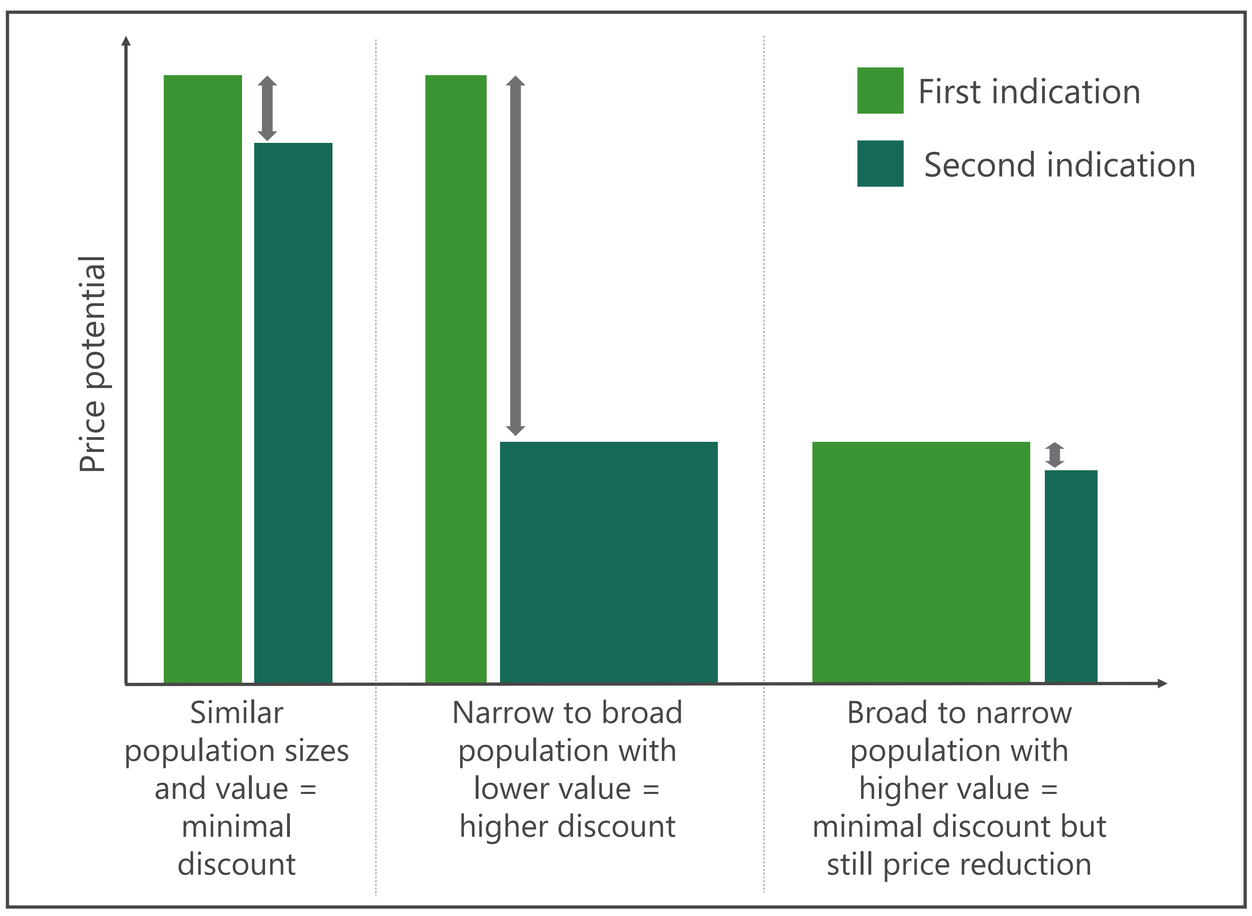

Table 1. Pricing mechanisms for indication expansions across the EU4 and UK

	Discount negotiations	Weighted pricing	Mandatory discount
France		✓	
Germany		✓	
Italy			✓
Spain		✓	
United Kingdom	✓		

- There is variation in the pricing mechanisms applied when assessing a product in a second indication across the EU4 and UK.
- In France, Germany, and Spain, a weighted price is applied across both indications with the population size and comparator products being key considerations in determining value.
- Mandatory discounts are applied in Italy proportional to the increase in population size, with unmet need, added clinical value, and quality of evidence also impacting the level of discount[2].
- In the UK, a new PAS is usually agreed and applied to both indications as the product will no longer be cost-effective at the existing PAS[3]. Differential discounting can be applied if the product meets criteria outlined in the NHS commercial framework and VPAG.
- These pricing mechanisms provide broad guidelines, but the final net price depends on the associated value, unmet need and target indication of the specific product.

CONCLUSIONS

Across the EU4 and UK, pricing mechanisms differ during indication expansions and the factors considered to determine the differential value versus the first indication have varying levels of influence on the discount applied. The net price of a product typically decreases when launching in a second indication as the population size and subsequent budget impact increases. However, it is important to consider the potential increased revenue associated with a greater patient volume. Overall, it remains important to tailor your launch strategy to each market to optimise price potential when expanding into additional indications.

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