PRICING AND REIMBURSEMENT ENVIRONMENT FOR A BIOLOGIC OBTAINING A LICENSE IN A SECOND INDICATION IN KEY EUROPEAN COUNTRIES

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INTRODUCTION

- In Europe, the reimbursement and funding process for biologic therapies is highly complex, with substantial differences between countries and further variations at regional and local levels in some countries. The process for a biologic obtaining a license in a second indication is even less clear

OBJECTIVE

- We sought to gain a better understanding of the pricing and reimbursement processes, and evidence requirements at national, regional, and local levels with regard to a biologic obtaining a license in a second non-oncology indication in the United Kingdom (UK), France, Italy, and Spain

METHODS

- In late 2013 and early 2014, we undertook a series of telephone interviews with payers and payer advisers (Table 1). These discussions lasted one hour and followed an interview guide that had been developed in advance
  - In countries with a largely national system and no major local variations in terms of funding flow for biologics (UK [England], and France), five telephone interviews were conducted
  - In countries with large variations at local and regional levels (Italy, and Spain), a greater number of interviews were conducted to capture these variations (18 and 17 interviews, respectively)

Table 1. Breakdown of Stakeholders Interviewed in Each Country

Country	Types of Stakeholders	N
	2 payer-advising clinicians (second indication sought) 1 payer-advising clinician (first approved indication) 1 hospital pharmacist 1 specialised commissioner	5
	2 payer-advising clinicians (second indication sought) 2 payer-advising clinicians (first approved indication) 1 head of hospital pharmacy	5
	From 5 key regions: Campania, Emilia-Romagna, Lombardy, Tuscany, Veneto[a] 4 payer-advising key opinion leaders (second indication sought) 4 payer-advising clinicians (first/second indication) 2 payer-advising clinicians (first approved indication) 4 hospital administrators 4 regional payers	18
	From 5 key regions: Andalucia, Basque Country, Catalonia, Madrid, Valencia[a] 2 payer-advising clinicians (second indication sought) 7 payer-advising clinicians (first/second indication) 2 hospital administrators 6 regional payers	17

[a]Where required to recruit sufficient stakeholders, experts from other regions were included

RESULTS

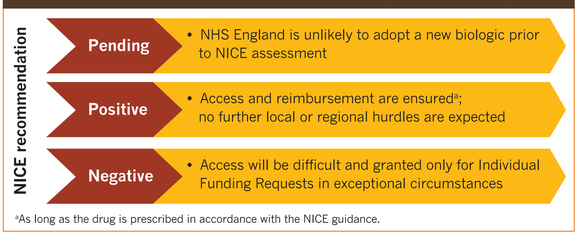
RESULTS: UK (England)

In the UK (England), the pricing and reimbursement process is agreed at a national level, with few restrictions at regional and local levels. National Health Service (NHS) England is likely to be responsible for funding of new biologics and relies on guidance from the National Institute for Health and Care Excellence (NICE) before adopting a product in a new indication; therefore, demonstrating cost-effectiveness is key

Reimbursement and Funding Flow for Biologics

- Reimbursement is agreed at a national level, following the recommendation issued by NICE
- Biologics are likely to be commissioned by NHS England, in agreement with NICE's recommendation (**Figure 1**)

Figure 1. Critical Role of NICE Assessment in the UK (England, Non-oncology Drugs)



[a]As long as the drug is prescribed in accordance with the NICE guidance.

Market Access Considerations

- Demonstrating cost-effectiveness is key to securing a positive recommendation from NICE
- Strategic consideration of Patient Access Schemes may be helpful in demonstrating acceptable cost-effectiveness

Considerations for a Second Indication

- The process is the same as that for a new drug (primary indication)

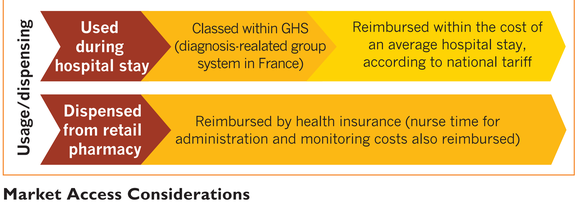
RESULTS: France

In France, the pricing and reimbursement process is agreed at a national level, with few restrictions at regional and local levels. Funding usually is through the groupe homogéne de séjour (GHS)

Reimbursement and Funding Flow for Biologics

- Reimbursement is agreed at a national level following the assessment by the Transparency Commission (TC)
- Funding depends on the intended usage or dispensing: drugs are reimbursed within the cost of an average hospital stay or by health insurance, as long as the drug is used within the Marketing Authorisation Application (**Figure 2**)

Figure 2. Funding Flow by the Mode of Dispensing in France



Market Access Considerations

- The amélioration du service médical rendu (ASMR) issued by the TC is important in achieving a high national price. The ASMR ranges from 1 to 5, where 1 corresponds to an innovative product of significant therapeutic benefit (for which a high price is possible) and 5 corresponds to no improvement (leading to a low price). This system is currently changing, however, and the service médical rendu (SMR)/ASMR system will be combined
- Pharmacoeconomic studies such as cost-effectiveness models may be required for high-cost drugs

Considerations for a Second Indication

- The process is the same as that for a new drug (primary indication)

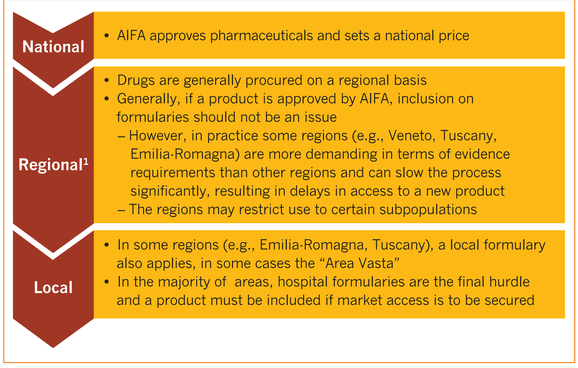
RESULTS: Italy

In Italy, the Italian Medicines Agency (Agenzia Italiana del Farmaco [AIFA]) must approve a new biologic on a national level, with further pricing and reimbursement decisions on regional and local levels. Evidence requirements vary at each level (national, regional, and local)

Reimbursement and Funding Flow for Biologics

- Reimbursement is agreed at national, regional, and local levels (with variation by region and sometimes by specific hospital) (**Figure 3**)
- Formulary decisions may be influenced by decisions taken in other regions or areas
- Regionally, biologics are funded according to their classification: Class A includes essential products and those for chronic diseases, these are fully reimbursed by the NHS; class H drugs are fully reimbursed in the hospital setting only
- In some regions (including Campania, Friuli, Lombardy, Sicily, and Veneto), biologics are funded through special funding "File F"

Figure 3. Pricing and Reimbursement in Italy (National, Regional, and Local Levels)



Market Access Considerations

- Regional formularies generally focus on efficacy and safety data, whereas local and hospital formularies require local epidemiology and budget-impact data
- If a product is considered an innovative medicine, patient access must be guaranteed across all regions

Considerations for a Second Indication

- The process is the same as that for a new drug (primary indication)

RESULTS: Spain

In Spain, once a drug is approved nationally by the Spanish Agency of Medicine (Agencia Española de Productos Sanitarios [AEMPS]), regions develop their own recommendations, and local decisions are made by hospital formularies. Evidence requirements vary at each level (national, regional, and local)

Reimbursement and Funding Flow for Biologics

- The pricing and reimbursement process is agreed at national, regional, and local levels (**Figure 4**). Drugs are then procured at a regional level and restricted by hospital formularies
- Reimbursement and coverage decisions at regional and local levels are influenced by health technology assessment, and pricing and reimbursement decisions from other regions in Spain, as well as other countries, such as the UK (NICE, Scottish Medicines Consortium [SMC]); Germany (Institute for Quality and Efficiency in Health Care [Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG]); and, to a lesser extent, Canada (Canadian Agency for Drugs and Technologies in Health [CADTH])

Figure 4. Pricing and Reimbursement in Spain (National, Regional, and Local Levels)

[a]In Valencia and Madrid, there is a patient copayment scheme for some patients or treatments (40%-60% of drug price); in other regions, the costs of drugs are fully reimbursed, but a copayment of approximately A5 for high-cost therapies is expected to be introduced in the near future. Aragon, Basque Country, Galicia, Madrid, and Valencia have a strong regional influence over local hospitals.

Market Access Considerations

- Data on efficacy and safety, comparative analysis with direct comparators, budget impact, cost-effectiveness, and epidemiology data are key at regional and local levels
- Performance metrics are important for expensive treatments (patients are closely monitored every 3 months)

Considerations for a Second Indication

- No changes are expected compared to a process for a new drug (primary indication), but the price in the second indication is expected to be reduced

CONCLUSIONS

- A biologic obtaining a license in a new indication must undergo the same process as a new product
- The processes and restrictions for biologics may be stricter than for other medications because of their perceived high cost
- The level of national, regional, and local requirements and restrictions varies; it is important that appropriate evidence is submitted to decision makers at each level

Acknowledgement
The authors thank Maninder Karka (Novartis) for designing the poster layout.

Funding
This research was funded by Novartis Pharma AG, Basel, Switzerland.

Presented at: Poster presented at ISPOR 17th Annual European Congress, 8–12 November 2014, Amsterdam RAI, Amsterdam, The Netherlands