Cogentia®

Pricing and Reimbursement Evidence Requirements for a Mature Pharmaceutical Product

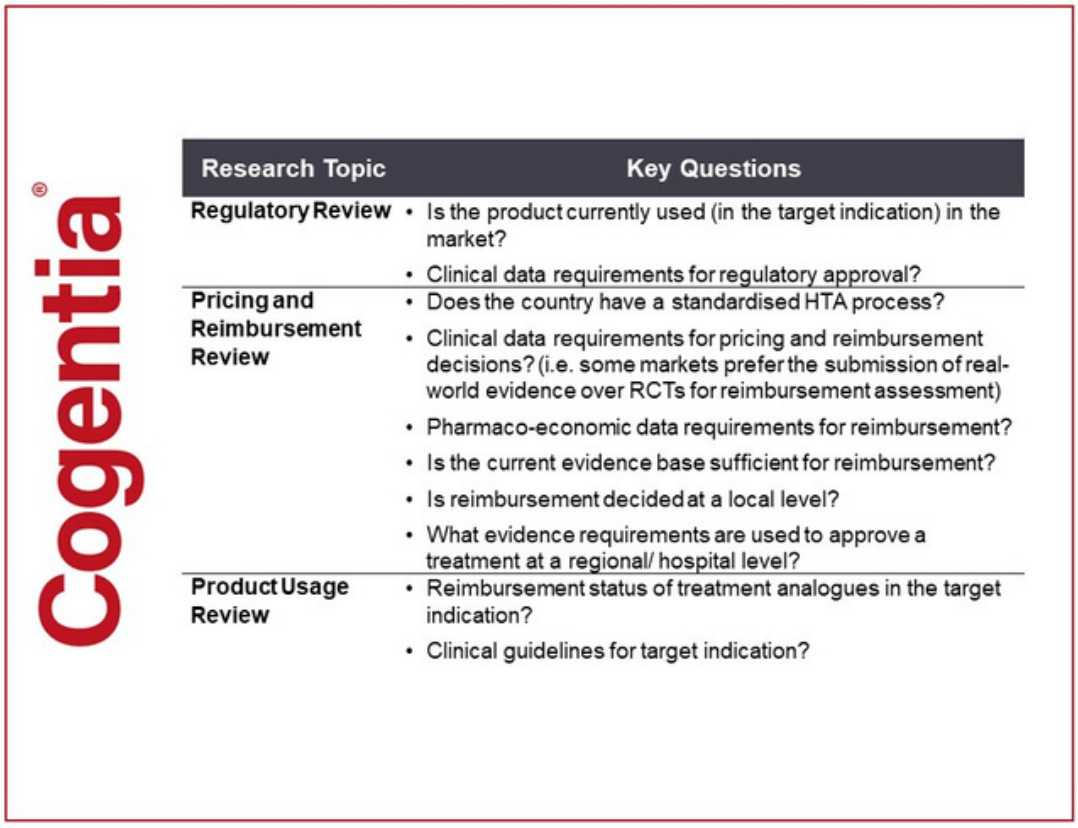
(May 2023)

Cogentia have recently conducted a global market review to assist our client in planning for a successful relaunch of their pharmaceutical product across a total of 40 scope markets.

The product in question is a branded therapeutic, which has historically achieved regulatory approval in many of these markets. Current clinical trial data includes both single arm and real-world evidence generation studies. However, due to the lack of clinical data specifically in the form of a randomised controlled trial (RCT), achieving reimbursement in most scoped markets has been a challenge.

Our client was in the process of considering future clinical trials to gather additional evidence and was keen to understand how the current and future evidence base would influence reimbursement decisions across each scope market. To guide our client's global product relaunch, it was essential to identify the barriers to achieving reimbursement in each market. This allowed us to provide our client with a detailed launch sequence and highlight the key markets to target.

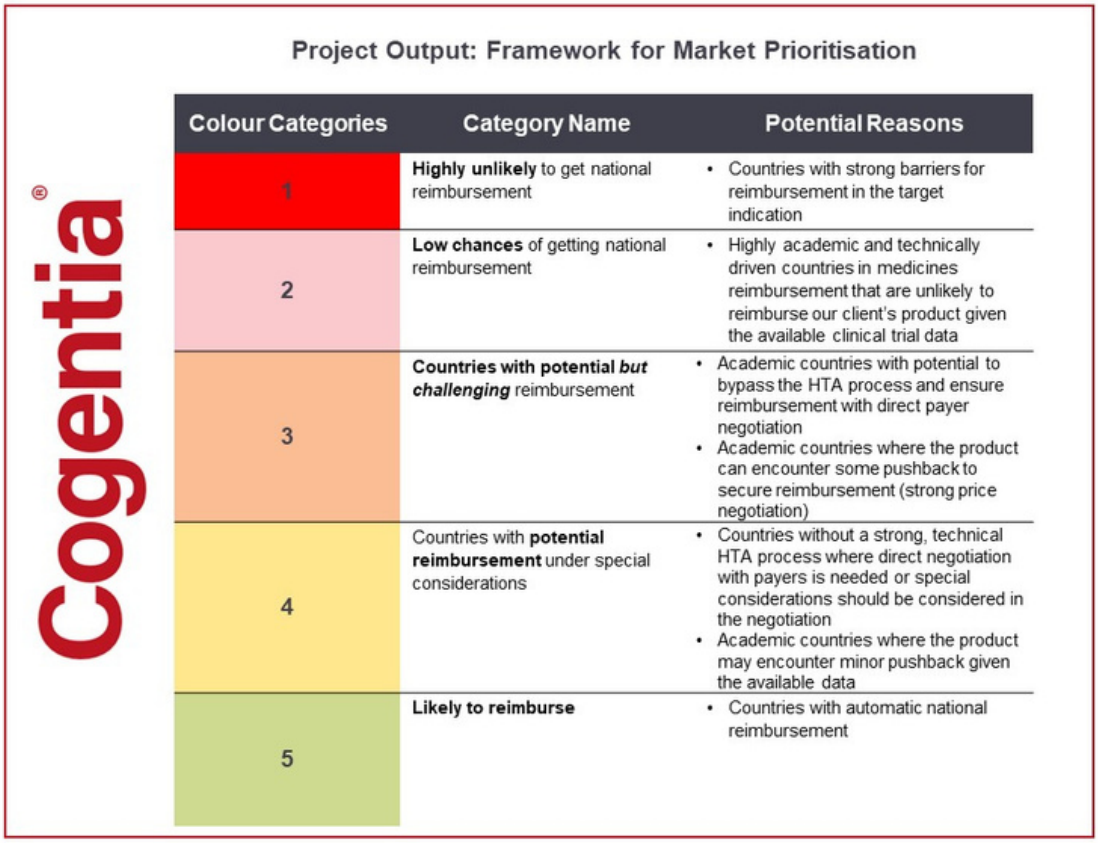
Cogentia began by reviewing the current evidence base and potential options for future evidence generation plans. A comprehensive research plan was then developed, and secondary research was conducted in each market based on the following questions:



Research Topic	Key Questions
Regulatory Review	• Is the product currently used (in the target indication) in the market? • Clinical data requirements for regulatory approval?
Pricing and Reimbursement Review	• Does the country have a standardised HTA process? • Clinical data requirements for pricing and reimbursement decisions? (i.e. some markets prefer the submission of real-world evidence over RCTs for reimbursement assessment) • Pharmaco-economic data requirements for reimbursement? • Is the current evidence base sufficient for reimbursement? • Is reimbursement decided at a local level? • What evidence requirements are used to approve a treatment at a regional/ hospital level?
Product Usage Review	• Reimbursement status of treatment analogues in the target indication? • Clinical guidelines for target indication?

The final project output was delivered within our client's desired timeframe, providing them with a product commercialisation and future evidence generation plan which included:

- A report summarising the evidence requirements for regulatory approval and reimbursement in each scope market
- A framework for market prioritisation with a traffic light system approach (shown in the table below) to reflect the likelihood and risks of a pricing and reimbursement decision for each scope market (i.e. allowing for identification of red flags for product commercialisation)
- A framework for market prioritisation with a traffic light system approach (shown in the table below) to determine the impact of each potential evidence generation plan on future reimbursement opportunities
- Our recommendations on which future evidence generation plan to select in addition to the current clinical evidence base to provide the best chance of achieving reimbursement in each scope market.



The above insights provided our client with the ability to confidently assess which scope markets to target/ avoid and which future evidence generation plan to select to increase the likelihood of product reimbursement.

FINDINGS

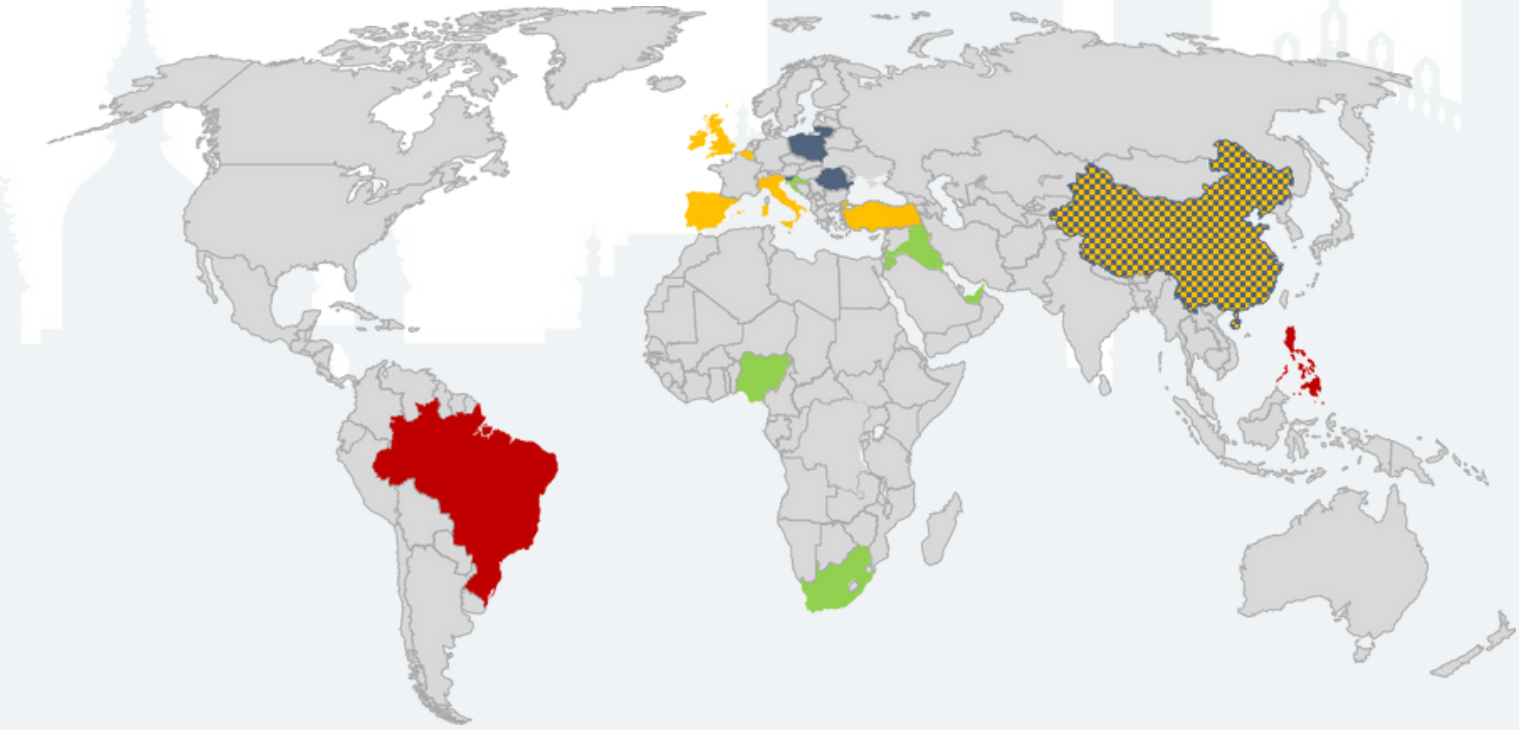
In this publication we will highlight four main project findings, we have group them into four different country categories:

Red Countries:
Two countries were clinical guidelines presented a negative recommendation to a product in the drug category, therefore they acted as red flags for the reimbursement of the drug class, resulting in a need to de-prioritise the market in launch planning.

Green Category:
Eight countries without a formal centralised national HTA process for national reimbursement, allowing for direct negotiation with hospitals to achieve partial reimbursement of their drug in these markets (given that the product effectiveness data lacked academic rigor, but the product was already used off label for the indication) – Nigeria, Iraq, UAE, Kuwait, Jordan, South-Africa, Luxembourg, Croatia (HTA process required in “paper”, but not “in practice”)

Yellow Category:
Six of the countries with centralized HTA process, that only review a prioritised list of new drugs, which opens the opportunity for direct hospital/regional negotiations for drugs that are not prioritised (usually due to a reduced budget impact or price). Turkey, Ireland, Belgium, China, Italy, UK (expected to change in 2023)

Blue Category:
Some countries preferred local data in reimbursement submissions, therefore proposed real-world single arm trials to collect local data would help the pricing and reimbursement negotiations – Slovenia, China, Romania, Lithuania, Poland



For Cogentia, facilitating market access to life changing therapies is a key part of our mission, and we remain committed to using our experience and knowledge in the area to support our clients in bringing their pharmaceutical treatments to market.

Our key market access offerings can provide support globally across a range of markets and include:

- Market understanding (i.e., market access landscaping, treatment pathways and guidelines analysis)
- Opportunity assessment (i.e., access pathway, route to market and portfolio decision making)
- Strategy development (i.e. market access strategy, evidence gap analysis and recommendations)

For more information about our offerings please visit https://cogentia.co.uk/services