Expectation vs Reality: Delayed reimbursement decisions due to increased budgetary pressures in Eastern Europe

Chris Teale[1], **Matteo Fabiani**[1]
[1]Ipsos MORI, London, UK

Objectives:

This study aimed to examine the "reality" of the pricing and reimbursement landscape, and the increasing budgetary pressures being caused by the COVID-19 pandemic, for new pharmaceutical products entering the market in Eastern European countries (EEu), with a specific focus on Janus Kinase inhibitors (JAKs) in the Rheumatoid Arthritis (RA) space

Methodology:

Desk research to outline a benchmark HTA evaluation and market access landscape in Bulgaria, Croatia, Hungary, Romania, Serbia and Slovenia

Telephone interviews were conducted with local or national payers across the 6 markets (n=11) to understand if the processes outlined by national laws are implemented differently in real-world practice

Results:

JAKs are reimbursed at a national level although distribution routes vary across markets between hospital and pharmacy settings. Patients have minimal out-of-pocket costs, as either the NHIF/MoH or manufacturers will cover costs of treatments.

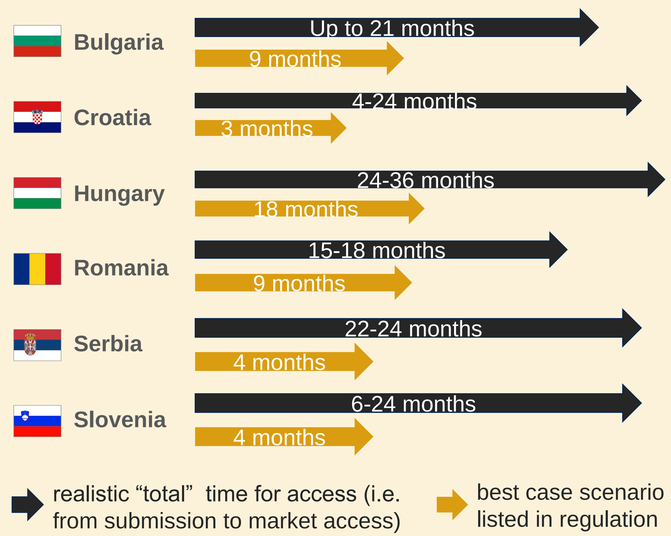
Figure 1: Funding routes for JAKs in EEu6 countries

Country	Reimbursement	Dispensation	Drug list/ class
Bulgaria	75-100% by NHIF and/or MAH	hospital	Positive drugs list (Annex 1)
Croatia	100% by CHIF	hospital	Expensive drugs list
Hungary	100% by NEAK	hospital	Positive drugs list (PDL)
Romania	100% by national healthcare budget	community pharmacy	Category C1 – ambulatory care for severe and chronic diseases
Serbia	100% by NHIF	hospital	Category C- expensive drugs list
Slovenia	100% NHIF	community pharmacy	Reimbursed list

hospital =community pharmacy

Our research highlighted that increasing budgetary pressures have led to an expectation of increased delays on reimbursement decisions in a number of Eastern European markets. In fact, reimbursement timelines across the EEu6 countries vary from between 6 months to 3 years depending on a number of different influential factors within markets

Figure 2: Comparing timelines listed in regulation and "effective" time to reimbursement across EEu6 countries



Market access hurdles for new JAKs are progressively decreasing, as clinician and payer awareness grows with the increasing availability of, and experience with, JAKs.

Although familiarity with advanced therapies grows and price erosion (including biosimilar price contagion) increases, bureaucratic delays are still the most common barrier to rapid access in these markets.

JAKs entering the market face several challenges, that can be overcome with the provision of relevant data and an appropriate pricing strategy.

Key hurdles for JAK launches in EEu6

Cost:
Cost is seen to be one of the key challenges for innovative treatments entering the market and reimbursement decisions are heavily driven by cost effectiveness

Budget impact:
Payers are mindful of the potential budget impact associated with high-cost drugs, as their usage continues to increase

COVID-19:
The pandemic has caused budgets to be tightened and governments to deprioritise approval of new therapies in areas that already have many existing treatments

Downwards price pressure:
Other JAK inhibitors are already being used and "forced" to lower net prices in line with TNFs

Treatment positioning:
JAK use is currently restricted to second line after TNFs

Conclusion:

For new products that are entering competitive treatment spaces to successfully undergo pricing and reimbursement assessment processes in a prioritised and timely fashion, there is an increasing need for companies to demonstrate strong clinical and cost effectiveness data. Additional considerations should also be made for: timelines, comparative evidence versus current standard of care, market size, competitiveness within a therapy area and biosimilar policies. All these elements have a critical role to play when manufacturers are developing product launch strategies.

Abbreviation: CHIF= Croatian health insurance fund; HTA= health technology assessment; MAH= marketing authorisation holder; MoH= Ministry of Health; NHIF= national health insurance fund; TNF= tumour necrosis factor;