Background and Objectives

• The global prevalence of diabetes reached 8.5% in 2014.1
• Gliflozins are SGLT2 inhibitors, a therapeutic class of drugs indicated for the treatment of type 2 diabetes mellitus.2
• Three products belonging to this class were granted marketing authorizations by the European Medicines Agency between 2012 and 2014: Invokana® (canagliflozin), Forxiga® (dapagliflozin), Jardiance® (empagliflozin).3
• However these drugs presenting an innovative mechanism of action faced heterogeneous market access outcomes on the European market.
• The purpose of this study is to understand the disparities of HTA outcomes for gliflozins in France, Spain, Germany and the United-Kingdom.

Methods

• To understand market access disparities, health technology assessments reports on gliflozins from HTA agencies in France, Germany, Spain and the United-Kingdom were compared.
• HTA-Accelerator™ platform was used to identify published evaluations of Invokana®, Forxiga®, and Jardiance®.
• The analysis was based on the type of evaluations, the submitted data, and the conclusions emerging from the assessments.

Results

• In Germany the BGA regulates drugs reimbursement and restrictions. Its assessment was unfavorable with negative recommendation as no added benefit was demonstrated. It outlined that the study population was different from the target population and that the submitted studies did not comply with recommended doses.
• The IQWiG evaluates the effectiveness of drugs. It gave positive recommendation with restrictions, mainly because it considered that the study comparator was inappropriate.
• In the UK, the SMC issued a positive recommendation with restrictions, as gliflozins were not recommended in monotherapy.
• The NICE had the same evaluation, but in 2016, gliflozins were recommended in a multiple drug assessment to be used in monotherapy for some patients.
• The AWMSG considered that Jardiance® presented good safety and tolerability.

Conclusion

• This analysis outlines that gliflozins have been assessed differently by these four European HTA agencies. Whereas HAS and GBA are looking at clinical benefit, NICE is considering economic impact as well. Then it is not surprising that a favorable recommendation from the NICE has been issued, knowing the pricing of these drugs.
• Although this new class of drug presents an innovative mechanism of action, considering the clinical assessment, the submitted data did not demonstrate their interest in the therapeutic strategy, and overall the European agencies considered that the benefit with gliflozins was modest on glycemic control.
• This raises the question of the relevance of a collaborative HTA pathway throughout Europe. Indeed, the EUnetHTA initiative could bring equal added value to healthcare systems and citizens at the European, national and regional level.