Research Briefing

Effectiveness factors in HTA reports concerning diabetes

Erpur Adalsteinsson; Mikkel Z Ankarfeldt; Clementine Nordon

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Introduction

We explored the requests for effectiveness evidence issued by HTA bodies in newly marketed anti-diabetes drugs, in order to get an understanding of how to take effectiveness factors into account earlier during the drug development process.

Methodology

All English speaking HTA assessments on anti-diabetes drugs (GLP-1 analogues, DPP-4 inhibitors and SGLT-2 inhibitors, except those with fixed combinations) available on 17 Nov 2015 were identified from the internet websites of NICE and SMC in UK, HAS in France and IQWIG in Germany. Comments regarding a need for effectiveness requirements were extracted from the reports. A qualitative and quantitative assessment of the comments was performed, using the PICO classification (population, intervention, comparator and outcome).

Results

In total 49 HTA reports were identified (8 HAS, 11 IQWIG, 5 NICE, 25 SMC). Most frequently, the comments were about the study population (n=22 reports). Examples’ being HAS often commenting need for French patients in studies and SMC demanding need for older patients in studies. Second most frequent comments were regarding the outcomes (n=21 reports). This was generally a wish for longer study duration including hard endpoints such as death or cardiovascular disease. Comments regarding choice of comparators were mainly found in IQWIG reports and comments regarding intervention were few and focused on drug titration. The only explicit requirements for real world studies came from HAS, which systematically requests post marketing study to be performed, for all drugs.

Discussion/conclusion

Most concerns were seen around the appropriate population in the trials, which is also the classical distinction of RCT and real world evidence. Both SMC and NICE accepts indirect comparisons and long term modelling and therefore their comments were focused around methodological aspects of these. This may have resulted in fewer requests around inappropriate comparators and outcomes.