WHAT THE ENGLISH COULD LEARN FROM THE IRISH
MAKING THE NICE APPROVAL PROCESS MORE COST-EFFECTIVE

INTRODUCTION
The National Institute for Health and Care Excellence (NICE) is a body that has garnered worldwide respect for its fully comprehensive clinical and economic review of pharmaceutical agents. However, it has been criticized for taking too long to conduct assessments and, as a consequence of this, only being able to appraise a subset of all new agents coming to market.

Other Health Technology Assessment (HTA) bodies achieve a much higher output of treatment appraisals with a much shorter turnaround time e.g. in 2013 NICE appraised 27 drugs compared to 57 by the National Centre for Pharmacoeconomics (NCPE), Ireland.

METHODS
A thematic analysis of the appraisal processes of the NCPE was conducted to determine if any key criteria could be extrapolated that could potentially increase the speed and output of the NICE appraisal process.

RESULTS
One particularly interesting aspect of the NCPE system was revealed — a 2 to 4 week rapid preliminary review that all drugs must undergo to determine the necessity of a full pharmacoeconomic assessment (PEA). Full PEAs are reserved for products with high cost, significant budget impact, and/or questionable value for money.

This enables products that are cheaper and at least as efficacious as the relevant comparator to gain rapid market access. It also enables the NCPE to focus their time and resources on the products that will have a substantial/questionable clinical and/or economic impact.

Case study: Giotrif (afatinib)
Background
• Afatinib is a Tyrosine Kinase Inhibitor (TKI)
• Afatinib was EMA approved in July 2013 in 1st line EGFR M+ NSCLC
• Two other TKIs approved in 1st line EGFR M+ NSCLC
  • Gefitinib [EMA approved 2009]
  • Erlotinib [EMA approved 2011]
• The supportive data package for afatinib
  • No RCT data vs. the other established EGFR targeting TKIs (erlotinib and gefitinib)
  • A pivotal trial (LUX-Lung 3) showed PFS benefits but no OS gain vs. platinum doublet
  • These benefits are in line with those demonstrated in the pivotal trials of erlotinib and gefitinib in this indication

Comparing the afatinib appraisals by NICE and NCPE
NICE National Institute for Health and Care Excellence
• The manufacturer tried to model an ICER vs. erlotinib and gefitinib based on a mixed treatment comparison
• NICE rejected this, instead constructing its own model on the basis of the same clinical efficacy
• Afatinib was approved on the basis of a patient access scheme in April 2014 that brought its average treatment costs in line with the other TKIs

NCPE National Centre for Pharmacoeconomics
• Reimbursement was granted following the 2-4 week rapid review process
• This implies that afatinib was submitted with a treatment cost that was comparable or less than that of the other TKIs
• This suggests that manufacturers will undergo a simpler and less costly evaluation with parity price in return for speedier market access

CONCLUSIONS
NICE should adopt a systematic rapid review procedure similar to the NCPE procedure into their appraisal process to better focus NICE resources where they are most impactful.

Further, this could also incentivise pharmaceutical companies to drop their prices to gain rapid market access in England and Wales rather than going through the expensive and time-consuming procedure of a full NICE submission.