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Topic of the paper: Comparative analysis of health care systems

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Title: R&D, Competition and Diffusion of Innovation in EU: the case of Hepatitis C

Background: the introduction of DAAs challenged countries' ability to pay for innovation and initiated a debate around affordability. Intellectual Property (IP) rights, including patents and Supplementary Protection Certificates (SPCs), were seen as a mechanism obstructing market competition and allowing developers to insist on high prices, so restricting payers' willingness and ability to give patients' access. The economic literature shows that IPs are required to incentivise investment in Research & Development (R&D). in this context, it becomes important to explore how different factors, including in-class in-patent competition and Pricing and Reimbursement (P&R) policies can help addressing the trade-off between short-term access (static efficiency) and long-term investment in R&D on innovative therapies (dynamic efficiency).

Objectives: to assess the impact of (i) IP protections as an incentive for R&D (ii) market competition, and (iii) other contextual factors, including healthcare system characteristics, on access to Direct Acting Antivirals (DAAs) for hepatitis C virus (HCV) in six European countries (France, Germany, Italy, Portugal, Spain and the UK).

Methodology: the study combined an economic framework modelling the role of SPCs on incentives for R&D and in-patent competition with analyses of treatment uptake (IQVIA) data on DAAs, to assess the degree of market competition, the rate and speed of adoption to DAAs between 2014Q1 and 2017Q2 in the selected countries. We also performed semi-structured interviews with national experts and stakeholders to identify factors, mainly related to characteristics of the healthcare system and its P&R mechanisms, affecting access to DAAs. Finally, we estimated health gains accrued by treated patients in each country, adapting economic models performed for the UK, to estimate health gains resulting from DAAs adoption and explore the role of the speed of access and degree of competition on patients' health outcomes.

Main Results: our stylised framework showed that in theory current R&D incentives based on IP protections in the EU can encourage in-patent competition, which can lead to price reductions (i.e. making new medicines more affordable). This holds when savings determined by lower prices due to competition exceed the higher expenditure the health systems pay during the SPC term, when generic entry is delayed.

The uptake analyses showed that competition within the DAA class was intense in European markets soon after the launch of the first-in-class treatment. This is shown by the fast uptake and evenly distributed market shares characterising some of the large markets (more than 5,000 patients treated each month). In these highly competitive markets effective commercial arrangements pushing prices down and favouring the uptake were agreed (e.g. Italy and Spain). However, it is also true that some countries concerned by the exceptionally large budget impact, imposed restrictions (i.e. UK) on patient numbers which had a negative impact on the speed of uptake.

Our estimates of the health gains showed that countries relying on market competition – providing full access to all DAAs available and negotiating prices of individual treatments –accrued higher QALY gains compared to those, implementing restrictions to control total expenditure on DAAs.

Conclusions: IP incentives for R&D did not prevent DAAs from having a high degree of in-class competition before patent expire. Although further research is recommended to show to what extent IP protection may encourage competition, in particular in the context of cures of infectious diseases, our study suggested that the use of SPCs can potentially be a win-win strategy for payers and developers. In-class competition had a positive impact on uptake and adoption of DAAs in the top-5 European countries. However, in-class competition is a necessary but not sufficient condition for early adoption and fast uptake of innovative medicines as there are other factors related to the performance of the new technology, characteristics of the healthcare system (such as its infrastructures to tackle a specific condition and the way patients are identified and followed through the system) and political factors, which can play a role.