Accepted Manuscript

Title: Late-stage pharmaceutical R&D and pricing policies under two-stage regulation

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PII: S0167-6296(16)30028-5
DOI: http://dx.doi.org/doi: 10.1016/j.jhealeco.2016.06.002
Reference: JHE 1941

To appear in: *Journal of Health Economics*

Received date: 4-9-2015
Revised date: 12-4-2016
Accepted date: 1-6-2016

Please cite this article as: Sebastian Jobjörnsson, Martin Forster, Paolo Pertile, Carl-Fredrik Burman, Late-stage pharmaceutical R&D and pricing policies under two-stage regulation, *Journal of Health Economics* (2016), http://dx.doi.org/doi: 10.1016/j.jhealeco.2016.06.002.

Late-Stage Pharmaceutical R&D and Pricing Policies under Two-Stage Regulation

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July 18, 2016

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Abstract

We present a model combining the two regulatory stages relevant to the approval of a new health technology: the authorisation of its commercialisation and the insurer's decision about whether to reimburse its cost. We show that the degree of uncertainty concerning the true value of the insurer's maximum willingness to pay for a unit increase in effectiveness has a non-monotonic impact on the optimal price of the innovation, the firm's expected profit and the optimal sample size of the clinical trial. A key result is that there exists a range of values of the uncertainty parameter over which a reduction in uncertainty benefits the firm, the insurer and patients. We consider how different policy parameters may be used as incentive mechanisms, and the incentives to invest in R&D for marginal projects such as those targeting rare diseases. The model is calibrated using data on a new treatment for cystic fibrosis.

Keywords: Pharmaceutical Pricing and Reimbursement; Rare Diseases; Optimal Sample Size

JEL codes: L5, H51, I11, I18

1 Introduction

The fast pace of growth of health care expenditure relative to GDP growth that has been experienced by most developed countries, especially prior to the global economic crisis (OECD,