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OHE SUBMISSION TO THE COMMITTEE ON HEALTH AND EQUAL OPPORTUNITIES OF THE HOUSE OF REPRESENTATIVES

Value-based pricing delivers the triple-win

The goal of pricing of pharmaceutical innovations is to ensure that patients can access medicines in a way that is sustainable for healthcare systems whilst also supporting a sustainable stream of innovation that delivers continuous improvements in the treatment options available for patients. Prices send signals to innovators about where to focus their R&D efforts, as well as determine the overall level of investment in health and expected value of innovation in the pipeline.

A value-based approach to pricing is based on the principle that prices should reflect the value of a new medicine to 1) patients, 2) health systems and 3) society versus the current standard of care. A value-based approach to pricing, therefore, means that healthcare systems appropriately reward innovation, and access to the most valuable innovations is prioritised. It also means that price signals are aligned with patients' and citizens' priorities, such that the expected value of innovation for a given level of investment is maximised. A value-based approach to pricing also ensures that the level of investment in pharmaceuticals, and level of expected innovation in the pipeline, reflects their value to society. Therefore, a value-based approach to pricing delivers the 'triple win': providing patients with access to the latest innovations, in a way which is sustainable for health systems, whilst ensuring that appropriate incentives exist to

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stimulate ongoing investment in the research and development of new treatments.

Any other pricing approach is less efficient in signalling what society values, and therefore incentivizing the right kind and amount and quality of innovation. In setting a rationale, shared, framework for rewarding innovation, a value-based approach to pricing serves as a useful starting point for policies designed to address related challenges, including how to ensure countries contribute fairly to rewarding innovation

The proposal currently under review in Belgium will fail to balance the needs of patients, payers and innovators. No doubt there can be improvements to the way in which pharmaceutical markets in Belgium – and elsewhere – operate but the proposed cost-plus pricing approach is both infeasible and would undermine the efficient functioning of markets. Many countries undermine the efficiency of health care and pharmaceutical markets through the use of tools to limit expenditure, policies to correct other market failures, or to achieve other policy objectives.

The mechanism for setting pharmaceutical prices varies across Europe but typically consider both the value of the new therapy and some assessment of budget impact. See our paper (Bell et al, 2023) for a summary of approaches taken. Value is most commonly assessed in terms of the incremental cost-effectiveness of a new treatment compared to the best available alternative – how much more the treatment costs per additional unit of clinical benefit. Although there is increasingly a call to consider broader elements of value, such as productivity benefits or carer impacts. Countries can establish a value assessment system which reflects the preferences of their society and assesses the value and cost-effectiveness of new products. This processes should ensure that prices of recommended products reflect the value they produce, and should support sending clear signals to innovators on the health system priorities.

I was requested by Patrick Prévot, Chairman of the Committee on Health and Equal Opportunities for a written opinion on the draft text and therefore I will limit my comments to the documents shared, rather than provide broader comments on the economics of the health care and pharmaceutical markets in Belgium.

Cost plus pricing is inferior to alternatives

The text lays out a proposal for Cost Plus Pricing (CPP) modelled on the price calculator developed by the Association Internationale de la Mutualité (AIM). CPP is the principle of setting the price of a product based on its costs of production plus a profit margin either as a percentage of the costs of production, or a fixed per unit profit. For example, the AIM price calculator on which this proposal is modelled uses a margin of 8% on total costs plus an additional 5-40% for innovative medicines.

When estimated for CPP purposes, costs of production typically include manufacturing costs, costs associated with regulatory processes and compliance, and overhead and other operational expenses (World Health Organization, 2020). Additionally, in the AIM price calculator this is the reported R&D cost of the drug in question divided by the patient population. Typically, the payer determines the acceptable mark-up or profit margin it considers "fair" – or sufficient to reward an appropriate fraction of global R&D investment. It is not clear how to determine an appropriate return which is "fair" and how the needs of patients, payers, and innovators are balanced.

CPP may be viewed as a tool for managing healthcare system sustainability, because, in theory, it provides a one-shot 'windfall' to payers by lowering the prices of products to their cost of production, even during patent protection. This proposal suggests that savings would be in the region of 20% or EUR 1 billion annually, although it is not clear how this analysis was reached when cost data have been made available.

However, as we have written about previously (see Bell et al 2023) there are better alternatives for managing affordability and rewarding innovation that are superior to this CPP approach.

Cost Plus Pricing is unfeasible

There are no agreed methods for ascertaining the costs of R&D, and any attempts to do so require so many assumptions as to produce very arbitrary estimates (Morgan, 2016; Schlander et al., 2021). Therefore, this crucial portion of the cost of producing innovation is either neglected or not accurately estimated in practice. This is because

scientific spillovers are unobservable and not feasible to accurately quantify (European Commission, 2019) for several reasons.

Firstly, it is unfeasible to link early-stage R&D investment to specific launched products.

Secondly, it is unfeasible to adjust by the cost of failures unless it is done, at least, at firm level failures or therapy area average, and finally, because in the best case, if the figure can be estimated, it is difficult to apportion global R&D investment to different countries in a fair way (Henderson and Cockburn, 1996; Wong, Siah and Lo, 2019; DiMasi, Grabowski and Hansen, 2016).

There is no consensus on the costs of R&D and the costs of medicines. Recent estimates for new nervous system agents ranged from $323 to $1,474 million, and for antineoplastic and immunomodulating agents from $2,052 to $5,366 million (Wouters et al, 2020). One reason that estimates vary wildly is that the cost of failures and the cost of capital can be as much as half of the cost of R&D. Ignoring these will therefore significantly distort the calculation of CPP.

Industry often gets accused of lacking transparency in the costs of R&D and/or production but this is largely because it is not technically possible to do this accurately at the product level. However, even if the data were available using this data would break the link between health gain (value) and price, sending the wrong market signals.

Cost Plus Pricing sends the wrong signals

Leaving aside these technical challenges, CPP is fundamentally flawed because it misdirects the incentives of innovators towards investing in those areas which are most profitable given the design of the cost-plus approach. For example, the areas with the highest R&D costs or the lowest risk of failure.

As far as I can ascertain from the text shared with me, there is no proposal to reward failures and only to compensate for the R&D associated with the product under price negotiation. At best this would lead to Belgium free-riding on global R&D expenditures by only rewarding products which come to market, and at worst it would skew innovation towards areas with lower risk of failure. Under this proposal the quality of innovation – in terms of the health gain delivered – has no

effect on the rewards for the innovator. Therefore, incentives for investors to fund the most clinically valuable R&D projects are minimal and we should expect to see less breakthrough innovation.

CPP also incentivizes inefficiency: there are no rewards to innovators for streamlining their R&D processes, especially if higher R&D costs translate to higher prices (Schlander et al., 2021). This means that less efficient innovators have a profit-making advantage, with negative implications for sustainability - beyond the initial windfall when CPP is first introduced - and overall societal welfare as societies' resources are used inefficiently. By extension, there is no incentive to minimise distribution or logistical costs or costs of production.

Not only this, but in comparison to a value-based approach to pricing, it is expected that healthcare systems using CPP would allocate resources less efficiently and that the quantity and quality of innovation and level of competition between novel medicines would be lower. Finally, as with ER, CPP promotes price convergence, and so its use would either create access and financial sustainability challenges for lower-income countries in the EU and globally or substantially undermine incentives for innovation.

Cost plus pricing may lead to negative consequences

The introduction of CPP in Belgium may lead to strategic behaviour on the part of biopharmaceutical companies. The most obvious response would be to delay the launch of new therapies in Belgium either to prevent price contagion to any markets which include Belgium in their external reference pricing basket, or to discourage other countries from adopting the same or similar approaches. This delay would have a negative impact on patients and the health of the population.

About the author

Professor Graham Cookson is Chief Executive of the Office of Health Economics.

A econometrician by training, Graham focuses on health system efficiency, policy evaluation, and pricing and reimbursement in pharmaceutical markets. He was written extensively on pharmaceutical

markets in Europe and the US, and is a global thought leader on the economics of pharmaceutical innovation.

Alongside his position at OHE, Graham is an Honorary Professor at City, University of London and is a Fellow of Royal Statistical Society, Higher Education Academy and member of Royal Economic Society.

He holds an M.A. from Oxford University, a post-graduate diploma from King's College London, and an MSc and PhD from Imperial College London. He began his career as a university academic including at King's College London and the University of Surrey where he was Professor of Economics & Policy and Head of the Department of Healthcare Management & Policy.

His current research interests include the measurement and determinants of productivity in healthcare especially labour productivity; the industrial organisation of healthcare especially tariffs and competition; real–world evidence in health economic evaluation; and big data in the health and life sciences. He is best known for this work on the economics of staffing and skill mix in the English NHS, which was critical to the development of the NICE Guidelines on Safe Staffing.

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All of the proceeds of this work is gift-aided to the charity and supports our research activities.

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