Policy

International referencing for the US: the unintended consequences

The Trump Whitehouse proposes international reference pricing

Against a background of very public drug price hikes and a growing public awareness of pharmaceutical pricing in general, the Trump Whitehouse unveiled in late October the latest in a series of “America first” policies.

The administration suggest that the US are paying an innovation premium and supporting access for other developed countries where prices are much lower. They want to level the field, to ask European countries to take a wider share of the costs of innovation, and to put the “American hard-earned dollar” first, ahead of propping up expensive socialised health services around the world.

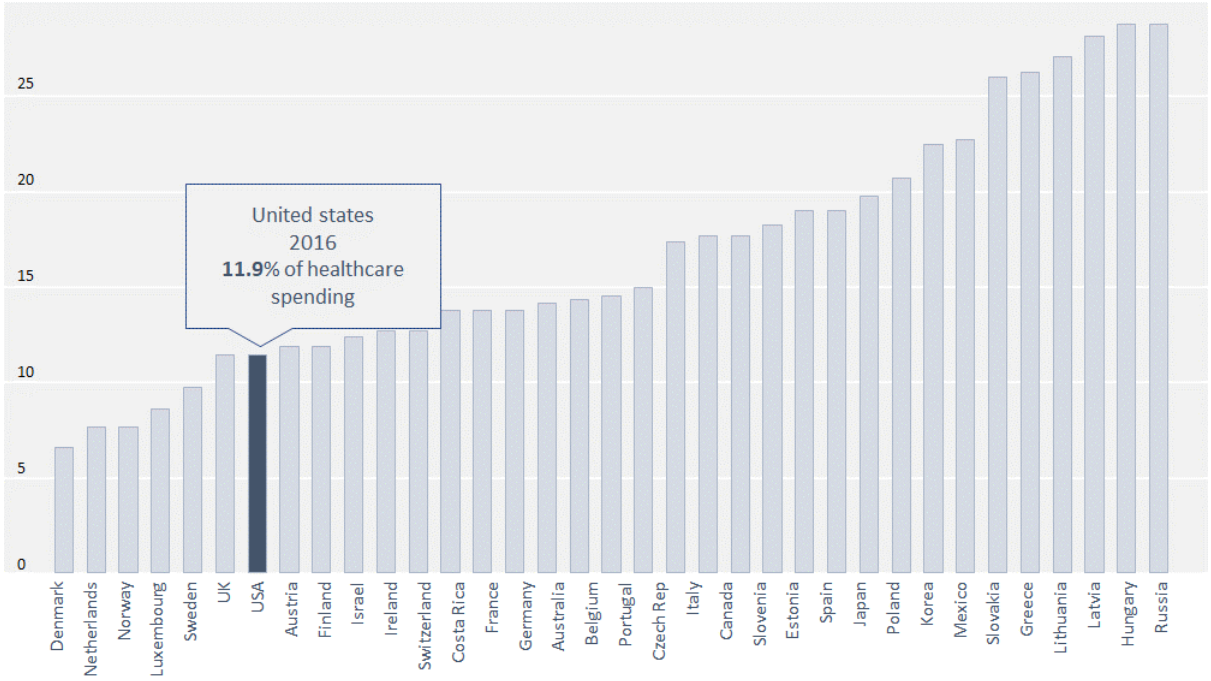
The suggestion is to introduce a form of international price referencing such that reimbursement in the US healthcare system is linked to a basket of prices in the EU.

Taking aim at “global freeloaders”, President Trump aims to walk a tightrope of reducing costs while maintaining a vibrant US pharmaceutical industry. Proponents of the plan suggest that the consequences of the move will be a drive for higher pharma pricing in the EU; but do the incentives and the rules line up? And what might the unintended consequences of the plan be?

The premise: the US pays a disproportionately high price for pharmaceuticals

Undeniably, drug pricing in the US does not resemble, in any way, drug pricing in the rest of the world, particularly Europe. Recent examples show the ugly face of US drug pricing –dramatic price hikes and unrepentant, and occasionally even offensive, senior leadership. However, the bad examples hide a myriad of carefully considered and executed pricing plans.

According to the OECD, US pharmaceutical expenditure in 2016 accounted for about 11.9% of its total healthcare expenditure. This compares quite favourably with all European countries – with only a few (Scandinavian markets, the Netherlands and the UK) spending a lower proportion. By contrast, 19 European countries spent more of their healthcare budget on pharmaceuticals – despite some of these being the countries with the lowest public drug pricing in Europe.



Ref: https://data.oecd.org/healthres/pharmaceutical-spending.htm

This is despite the fact that, unlike countries with socialised, universal healthcare systems, the pharmaceutical industry in the US has elaborate and expensive patient assistance programmes designed to help those most in need and unable to access medicines through private or government insurance programmes.

So, while true that the US may pay a disproportionate amount for healthcare, the case for disproportionate spend on pharmaceuticals is far from clear.

"Global freeloaders" and the innovation premium

The stated target of the initiative, as part of the "America first" programme, is to generate a greater global equality – if the world wants innovation then the world should pay. The expectation, stated by supporters of the reform, is that Europe raise drug prices to pay for pharmaceutical innovation.

This goal, however, assumes two key points:

- There is an incentive for European payers to change policies and processes to meet the US demand
- The European systems and processes can adapt to accommodate this demand

Let's take the second point first. With a few very unusual exceptions, European payer evaluations and reimbursement systems are neither designed nor allowed to accommodate price increases for in-market pharmaceutical products. To make a change there would frequently need to be legislative change and, even in the most liberal economies, at least a change in policy both at macro level and in the detail of execution. The current processes and laws prevent price rises or make them very difficult to enact; to change this would require an enormous effort at the national level for all European countries.

For products coming to market, Europe generally operates in one of several incremental improvement premium models (including cost-effectiveness thresholds and relative clinical assessments linked to formulaic pricing approaches). To have a substantial shift in the price point for pharmaceuticals in Europe, the industry would need the bargaining power to shift these deeply ingrained approaches and thresholds. There is little evidence to suggest that the industry possesses the negotiating power to do so – despite the threat of limitations in patient access to newer and very efficacious products.

So, is the incentive to change high enough?

In all likelihood, the impact of these reforms will be felt initially in the US and by the pharmaceutical industry through changes in pricing structures and impact on the domestic, non-Medicare/Medicaid market. The industry cannot change the pricing of in-market products in Europe and price shifts in the US will have a massive impact on pharmaceutical company profitability and business models.

A few European countries house significant non-commercial pharmaceutical investment, but this is generally limited. The European Federation for the Pharmaceutical Industries and Associations (EFPIA) estimates that 745,000 people are employed in Europe by the pharma industry, of whom 115,000 are in research and development roles – the rest are predominantly in commercial roles supported by the current economics of European pricing and pharmaceutical volumes. By contrast the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) estimates that 854,000 people are employed by the pharmaceutical industry in the US; 117,000 of whom are in R&D. Any changes in investment will disproportionately hit the US in the first instance – where substantial commercial operations will need to be scaled back to meet the new commercial reality of lower priced in-market products.

The likely consequences

Global pharmaceutical Armageddon is not likely to be delivered on the industry overnight – no one has an incentive to decimate the pharmaceutical industry – but the consequences for industry would still be significant.

If adopted, prices in the US are likely to drop by 25–35% to meet European averages. The immediate impact will be a necessary restructuring of commercial operations in the US. There will also be a higher threshold set for products to go through the R&D process. Already, future-thinking pharma companies are working harder than ever before to understand the likelihood of achieving access at a sustainable price even before first-in-man studies. When designed and executed well, early modelling can help make development decisions and prioritise assets and indications. With the US referencing European markets, this prioritisation will become even more important and more ruthless. The impact will be fewer marginal, rare, difficult-to-treat diseases being studied.

For European teams launching new products, the potential impact on the US will become acute and will embed a conservatism in pricing decisions beyond what already exists. If launching in Europe at a discount to the US impacts the total returns and shareholder value, then the companies will not be able to justify the launch and will become entrenched asking Europe for higher prices. The consequence for patients will be delayed access, for healthcare systems diminished ability to construct collaborative approaches to access, for the industry diminished global profitability and for

the US – ironically – a greater pressure to support the R&D costs as European launches are delayed, perhaps indefinitely.

Conclusion

Evolving the pricing model for the pharmaceutical industry globally is a key priority for all stakeholders – including the industry itself. Developing new ways of assessing and rewarding value are critical – not innovation for innovation's sake, but opening the possibilities for new approaches to medicine and outcomes that could only be dreamt of only a few years ago. This is a complex task and subtle changes can have long-reaching impacts.

Seductive but overly simplistic approaches can create perverse incentives and drive behaviours which are destructive not just to the initial objectives but the interest of patients. The industry needs to get ready for change, to counter simplistic proposals with sophisticated and well-considered approaches that allow affordability and sustainability in all healthcare systems.

Brace yourselves, look deep at the development pipeline and understand where value is coming from, build better data sets and get ready for big changes – either this one, or the ones that follow.

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