Improving patient access to innovative medications while protecting budget sustainability: an alternative go-to-market and pricing framework to enable value co-creation between pharmas and payers

Lor S. [1], Marville A. [1], Bourel G. [1], de Vaugelas A.[1], de Neuville B. [1], Floch O. [1]

[1]OpusLine, Paris

Background

Over the past decade, pharmaceutical companies have faced challenges directly affecting their P&L:

69% Increase in trial duration in major therapeutic areas such as oncology between 2002-2014

35% Increase in trial complexity (e.g. # of sites, endpoints multiplicity) between 2013-2018

51% Decrease in commercialization time before first follow-on entry between 1998-2011

This new environment has cornered pharmaceutical companies to use price increase, their main lever available to maximize ROI from drug development and commercialization programs:

20% Average price increase in EU between 2014-2017 as per a study conducted by the TLV

However, with increased pressure to reduce healthcare budget, this lever is becoming harder to pull thus creating a *status quo* between payers and pharmaceutical companies during Health Technology Assessment (HTA) and pricing. Ultimately, patients may be the first victim of such misalignments with significant inequities in treatment access across the EU:

69% Increase in time to market access following EU marketing authorization between 2010-2017

48% Average drug availability reported between 2015-2017 across the EU

It is hereby argued that patient access to innovative treatments, budget sustainability and R&D productivity can only be improved through a deep change in the model including incentivization – for both pharmaceutical companies and payers – to accelerate and increase the efficacy of pharmaceuticals' market access which would revitalise ubiquitous treatment access leading to a sounder structure and more importantly better patient outcomes

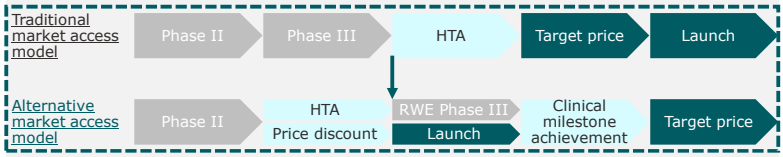
Objectives

We would like to discuss the potential of an alternative HTA and pricing framework to deliver shared value among payers, patients and pharmaceutical companies. It combines three key concepts:

1 Shorter trial programs to ensure positive B/R ratio in real world

2 Progressive pricing over time with a set price target

3 Real world demonstration of incremental clinical value



Our work aims at evaluating for each group of stakeholders the benefits resulting from such an approach as well as the associated challenges for actual implementation:

Patients | Payers | Pharmas

Methods

To conduct our research, we used seven drug benchmarks to qualify and quantify the potential impact of our go-to-market approach across different stakeholders. To estimate the impact we simulated an alternative drug lifecycle and calculated the resulting NPV, using the key hypotheses described below. In addition, we complemented this modeling with payer interviews from EU markets.

R&D cost reported from the PhRMA | Price parity with Phase III comparator at launch | RWE duration similar to the pivotal Phase III | Target price parity with current drug price level | Volume forecast based on reported global sales | Commercial launch from EMA approval | 10% discount rate in the NPV calculation

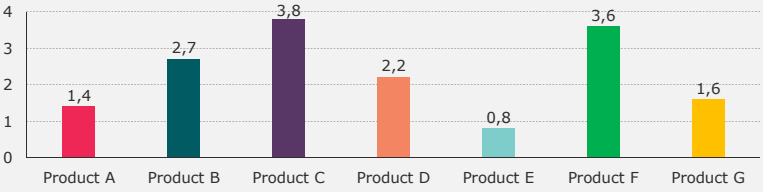
Product A	Product B	Product C	Product D	Product E	Product F	Product G
Rare cancers in HemOnc with growing competition	Solid tumor with long OS with growing competition	Solid tumor with long OS with large competition	Ultra orphan disease with no treatment alternative	Underserved solid tumor with growing competition	Solid tumor with long OS with large competition	Underserved solid tumor with growing competition

Results

Patients

Given the current market access context, patient benefits would mainly consist in faster market access as well as broader patient eligibility:

Years saved compared to current time to market estimates



The proposed framework allows for earlier market access following phase II resulting in significantly faster patient access to treatments:

68% Faster marketing approval in average without conducting a formal phase III trial; given the real life evaluation nature of the framework, the HTA process itself could be shorter too

However, payers suggested that depending on the drug and disease context it is of utmost importance to adapt the evidence generation plan accordingly:

If treatment alternatives are available, payers expect early Phase III results with surrogate endpoints and comparative data (e.g. light study looking at response rates)

In the absence of satisfying comparator (i.e. no treatment alternative, limited experience with the comparator) it is acceptable to provide non comparative Phase II results

Therefore, we see two main opportunities to leverage our approach, with drugs with no treatment alternatives or drugs facing a competitive environment in long OS diseases

Payers

From a payer perspective we can estimate the actual benefit of this alternative approach focusing on the potential annual impact budget savings:

Impact of target price level variations on drug annual budget savings

	-60%	-50%	-40%	-30%	-20%	-10%	Current
Product A					-19%	-9%	
Product B					-17%	-6%	
Product C					-12%	-1%	
Product D				-16%	-4%		
Product E					-12%	-1%	
Product F			-22%	-9%			
Product G					-20%	-10%	

Lower impact vs. baseline | Higher impact vs. baseline | X% Annual budget saving | X% Reduction on the target price

The proposed framework would increase drug commercialization time prior to loss of exclusivity or first follow-on entry:

The progressive pricing framework would mitigate the budget impact increase from a longer time on market resulting in similar annual budget impact levels

However, if drugs were to reach target price levels similar to the current ones following RWE demonstration of their value, our approach would not yield budget savings for payers

10% The minimum discount level on the target price that would generate budget savings on a yearly basis is a 10% discount vs. current price levels for most drugs

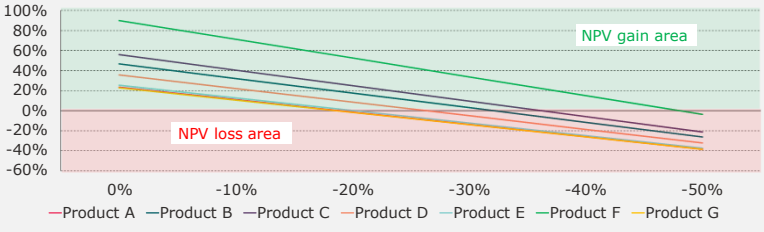
Therefore, maintaining or decreasing annual budget impact with our alternative approach would require to temper target price ambitions from a pharmaceutical company perspective:

This would only be realistic if our approach could deliver ROI gains despite lower target price levels, which could be modeled through the Net Present Value of each R&D program

Pharmas

Finally, from a pharmaceutical company perspective, we estimated the Net Present Value variation using our alternative approach compared to the current baseline NPV:

Impact of target price level variations on drug NPV vs. current NPV estimates



The proposed framework has potential to increase the estimated NPV of a R&D program despite the associated progressive pricing approach (up to the current price levels):

24% Average gain in NPV for drugs with short survival rates (i.e. products A, E and G) despite modest gains anticipated from a time to access perspective (i.e. less than 18 months)

60% Average gain in NPV ranging from 36% (i.e. products D) to 90% (i.e. products F) for drugs targeting diseases with longer survival thus requiring longer Phase III trials

In addition, we tested a range of price discounts applied to the target price and also found that NPV gains were still possible when lower target prices (vs. current prices) were agreed:

10% All drugs in our model would deliver NPV gains at 10% discount vs. current price levels

30% In addition, drugs targeting longer OS cancers would still deliver NPV gains at higher discount levels until 30% discount vs. current price levels

Our model could facilitate price negotiations between pharmas and payers; making lower price targets possible would strive for one unique EU price be enforced across the EU

Conclusion and discussion

With ground breaking drugs (e.g. gene therapies, BCMA engagers) soon to reach the market, it is time to advocate for a new go-to-market model that would allow shared value among all stakeholders. Our approach, if used in appropriate situations, can accelerate patient access, increase one R&D program's commercial opportunity while limiting its annual budget impact

By essence it could be implemented at the EU level and contribute to shaping a joint HTA and pricing process leveraging a "real-world Phase III" that would allow comparison vs. any standard of care in any market and a progressive pricing approach that would offset the investment risk yielded by initially reimbursing a drug at its full price, thus fostering broader and faster access across EU

However, the path to implementing this new model remains challenging and requires a change in mindset as price cannot increase over time, transparency and information sharing between markets to disclose net prices agreed at national levels to define a reference frame, and commitment from payers to increase price along with clinical milestone achievements or clear sanctions otherwise

Contacts:
Olivier Floch, Partner | email: olivier.floch@opusline.fr
Bertrand de Neuville, Managing Director | email: bertrand.deneuville@opusline.fr