

# Pathways to Value: Pharma in a Changing World

## Executive Summary

### Health Systems in Flux

This report examines world-wide health reforms and their implications for pharmaceutical reimbursement. It is the outcome of an innovative and high-level series of workshops bringing together leaders from the pharma industry, their investors and key health system executives.

The starting point of the report is the wave of health reforms that are transforming health systems globally. They are introducing new measures of accountability for evaluating and delivering health outcomes, and ways to improve and measure productivity. They seek to contain rising healthcare costs and to apply increasingly sophisticated use of complex data to measure the impact of health interventions. In some places, greater importance is being placed on the role of the patient in

understanding clinical effectiveness in the real world and determining value. These reforms are changing perceptions of what offers value to health systems and as such they are highly relevant to pharma.

### Pharmaceutical R&D

The reforms coincide with early indications of an upturn in pharmaceutical R&D productivity. The combination of promising research and health reform offers a real opportunity to develop a more agile and cost-effective system for drug discovery, development, licensing and usage.

### The Goal

The goal is to achieve greater understanding of what works, for whom, and at what stage in the disease pathway. To achieve this goal, today's binary decision-making at the point of regulatory approval and price setting would

need to be replaced by iterative, dynamic decision-making that adapts as evidence is accrued, and value determined over time.

### From Key Decision Points along the Value Chain

Collaboration along three key decision points in today's pharmaceutical development could make a huge difference. First, collaboration is required during the process of building evidence for a drug, where it is important to work out how to combine the safety and efficacy data generated in randomised clinical trials with evidence of clinical effectiveness in the real world. Second, today's zero-sum approach to authorisation could be replaced with a model of adaptive licensing sufficiently robust to guarantee safety and efficacy on approval, at the same time as being sufficiently flexible

to allow for iterative evidence-building over time. Third, pricing models could be adjusted away from today's fixed price point to ones that reflect changing perceptions of the absolute and relative value of a medicine based on evidence accrued as it is used in clinical practice.

### Moving To A Systemic Approach

Achieving these changes will not be easy. Strong leadership to encourage collaboration, build mutual understanding and build trust will be essential. Enlightened executives across the system will need to champion and endorse new ways of working in order to overcome the practical and cultural challenges involved in change. They will need to require their personnel from all parts of the system to collaborate on new approaches to value definition;

to enter negotiations with a better understanding of the constraints and pressures faced by their counterparts across the table. Finally they will need to overcome mistrust by encouraging people to recognise positive change where it is taking place and to take action on those behaviours that continue to create mistrust.

### Support of Investors

The pharma industry can only fully engage with these changes in its business environment if it has the support of its investors. Companies cannot predict what their returns will be, but they can explain the investment case for undertaking adaptive licensing or risk-sharing price deals in ways that resonate with investors. This includes the potential for earlier cash flows, less regulatory risk and less reimbursement risk.

### The Prize

Health systems, pharma and their stakeholders face a strategic choice. To ensure that evidence-based decision-making is embraced as an opportunity to agree the true value of pharmaceuticals – with all the implications this has for transparency, pricing and collaboration on outcomes. Or to perpetuate a problematic zero-sum approach to value definition which encourages mistrust and antagonism.

Replacing today's model of drug development and reimbursement with a new systemic approach would reduce the risk and cost of bringing a medicine to market and increase the likelihood that the medicine will improve productivity and patient outcomes. This result is a value proposition that works for all.



The *PharmaFutures* series was created in 2003 to allow institutional investors to hold a sustained dialogue with senior pharmaceutical managers to discuss the importance of societal expectations in shaping pharma's ability to generate long-term value. *PharmaFutures* seeks to achieve this end by encouraging frank, open and constructive exchanges between people who hold widely differing views and by building trust and collaboration between them.

At the core of *PharmaFutures* dialogues is a Working Group, formed of senior pharmaceutical executives, institutional investors and health system representatives from within the different markets. These dialogues are enhanced by a range of interviews with senior experts, and by extensive desktop research. This report concludes the fifth *PharmaFutures* dialogue, which ran from 2011 to 2013 and focused on the changing reimbursement landscape, and the global implications of trends in Europe, Emerging Markets, and the US.

*PharmaFutures* is convened by Meteos, a not for profit company that combines agenda-setting analysis, with senior level dialogues between industry, investors and societal stakeholders, to accelerate solutions to a range of systemic challenges.

#### Disclaimer:

As a multi-stakeholder and collaborative project, the findings, interpretations and conclusions expressed herein may not necessarily reflect the views of all members of the Working Group who took part in this project in their personal capacity. The report was compiled for information purposes only and it is not a promotional material in any respect. The material does not offer or solicit the purchase or sale of any financial instrument. The report is not intended to provide, and should not be relied on for accounting, legal or tax advice or investment recommendations.

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